

1 sodium thiopental is properly flowing into the inmate and that he is properly anesthetized prior to the  
2 administration of the pancuronium and potassium.

3 25. In my opinion, having a properly trained and credentialed individual examine the  
4 inmate after the administration of the sodium thiopental (but prior to the administration of  
5 pancuronium) to verify that the inmate is completely unconscious would substantially mitigate the  
6 danger that the inmate will suffer excruciating pain during his execution. As discussed later in this  
7 affidavit, this is the standard of care, and in many states the law, that is set forth for dogs and cats and  
8 other household pets when they subjected to euthanasia by potassium injection. Yet Procedure No.  
9 770 does not provide for such verification, and indeed actively prevents the injection team from  
10 determining whether or not the inmate remains conscious by requiring that all of the drugs must be  
11 administered remotely, from another room.  
12

13 26. By requiring that the drugs be administered remotely, Procedure No. 770 necessitates  
14 the use of multiple 72-inch extension sets of IV tubing. This unnecessarily increases the risk of  
15 leakage and/or pinching of the tubes, and therefore creates a greater risk that the inmate will not be  
16 properly sedated. Any reasonable standard of care would require a system to be in place to ensure  
17 that the prisoner is properly anesthetized.  
18

19 27. Procedure No. 770 provides no specifications regarding the timing of the  
20 administration of the drugs, thereby compounding the risks described in this Declaration. This  
21 concern is greatly amplified by the use of an ultrashort-acting barbiturate and is borne out by a  
22 review of the execution records from San Quentin. In each of the executions, the time between  
23 administrations of the three drugs varied for no apparent reason. The lack of a defined schedule for  
24 the administration of the three drugs increases the risk that the sedative effect of the sodium  
25 thiopental will wear off, should the inmate not receive the full dose.  
26

27 28. California's lethal injection protocol does not account for procedures designed to  
28 ensure the proper preparation of the drugs used. I have not seen details regarding the credentials,

1 certification, experience, or proficiency of the personnel who will be responsible for the mixing of  
2 the sodium thiopental from powder form, or for the drawing up of the drugs into the syringes.  
3 Preparation of drugs, particularly for intravenous use, is a technical task requiring significant training  
4 in pharmaceutical concepts and calculations. It is my opinion based on my review of lethal execution  
5 procedures in states that have disclosed more detailed information than what I have seen about  
6 California's procedures, that there exist many risks associated with drug preparation that, if not  
7 properly accounted for, further elevate the risk that the drug will not be properly administered and the  
8 inmate will consciously experience excruciating pain during the lethal injection procedures.

9  
10 29. One of the two alternative methods of injection allowed by Procedure No. 770 dictates  
11 that "the lip of the neoprene diaphragm on the "Y" injection site shall be rolled back so that it can  
12 easily be removed for insertion of syringe tips instead of a needle." Although Procedure No. 770  
13 does not articulate what type of "Y" site equipment is being used so I am unable to specify if this  
14 procedure is likely to cause a disruption in the intravenous flow of drugs, I am unaware of any such  
15 medically approved use of this equipment, and would not alter the site myself in such a fashion.  
16 Normal medical practice is to insert the needle or needle-less injection device through the diaphragm,  
17 thereby assuring a tight and adequate connection. This departure from standard practice is not  
18 explained, nor is it clear how this deviation was developed, or why.

19  
20 30. The altering of established medical procedures without adequate medical review and  
21 research, by untrained personnel, causes great concern about the structure of the lethal injection  
22 protocol and its medical legitimacy. There is no indication of how Procedure No. 770 was  
23 developed, who was consulted, what procedures were considered and why. The protocol may be  
24 something the Warden developed alone, or in consultation with other corrections personnel, some of  
25 whom may or may not have any medical training, or any specialized knowledge of anesthetic  
26 literature and practice. Appropriate mechanisms for medical review, and standardization of the  
27 implementation and amendment process, are critical features in any medical protocol so that the  
28

1 medical professionals and the public can be assured that proper and humane procedures are in place  
2 and being followed. Indeed, in other states, physicians and other medical personnel play a role in  
3 ensuring that any protocol is consistent with basic medical standards of care and humaneness.  
4 Otherwise, the process is subject and prone to ad hoc administration and error, if not gross  
5 negligence, or worse, an alteration of the process so as to inflict as much agony as possible. With  
6 lethal injection, such concerns are highly elevated.

7  
8 31. Procedure No. 770 unnecessarily calls for a saline solution to be administered between  
9 the pancuronium bromide and the potassium chloride. I do not see a medical purpose for this to be  
10 included in the procedure, and question whether it is necessary to achieve the goal of a humane  
11 execution. Moreover, it can create a risk of critical errors including medication errors caused by  
12 syringe "mix-ups."

13 32. There are no procedures contained within Procedure No. 770 for the resuscitation of  
14 the inmate once the sodium thiopental is administered. This would foreclose the possibility of  
15 altering the course of an execution in the event of legal relief. Any time up until the potassium  
16 chloride is administered, the prisoner could be readily resuscitated given the appropriately trained  
17 personnel and routine resuscitation medication and equipment. If this were to occur after the  
18 potassium chloride was administered, resuscitation would be more challenging but still possible.  
19 Resuscitation would therefore require equipment close-by, and properly credentialed personnel,  
20 neither of which are specified in Procedure No. 770.

21  
22 33. The information available to me about CDC's lethal injection execution protocol  
23 contains no reference to plans for dealing with the foreseeable circumstance wherein peripheral  
24 intravenous access cannot be obtained in the arm or leg. Based on my medical training and  
25 experience, and based on my research into lethal injection procedures and practices, it is my opinion  
26 to a reasonable degree of medical certainty that any reliable, humane lethal injection procedure must  
27 account for the foreseeable circumstance of a condemned inmate having physical characteristics that  
28

1 prevent intravenous access from being obtained by a needle piercing the skin and entering a  
2 superficial vein suitable for the reliable delivery of drugs. There have been multiple lethal injections  
3 in which this problem has arisen from a variety of circumstances. Some of these circumstances could  
4 be due to conditions including obesity, corticosteroid treatment, history of intravenous drug use,  
5 history of undergoing chemotherapy. Additionally, some people happen to have veins that are too  
6 small or deep to permit peripheral access. It is often not possible to anticipate difficult intravenous  
7 access situations, and there are multiple examples of executions in which the "IV team" struggled to  
8 obtain peripheral IV access and eventually abandoned the effort. Procedure No. 770 is deficient in its  
9 failure to plan for the foreseeable possibility that peripheral IV access can not be obtained.  
10

11 34. In this setting, state lethal injection protocols typically specify the use of a "cut-down"  
12 procedure to access a vein adequate for the reliable infusion of the lethal drugs. No equipment or  
13 supplies for performing a cut-down procedure are listed in the California lethal injection protocol, nor  
14 is there information regarding the training, experience, expertise, credentials, certification, or  
15 proficiency of the personnel who would perform such a "cut down" procedure. In this regard, CDC's  
16 lethal injection protocol is deficient in comparison to those of other states that I have reviewed. This  
17 complicated medical procedure requires equipment and skill that are not accounted for in Procedure  
18 No. 770. It has a very high probability of not proceeding properly in the absence of adequately  
19 trained and experienced personnel, and without the necessary equipment. If done improperly, the  
20 "cut-down" process can result in very serious complications including severe hemorrhage (bleeding),  
21 pneumothorax (collapse of a lung which may cause suffocation), and severe pain. It is well  
22 documented that lethal injection procedures in other states have at times required the use of a central  
23 intravenous line. The defendants have not, to my knowledge, released information about the need for  
24 central intravenous access during prior executions, and therefore it is not possible to make any  
25 assessment about whether the necessary safeguards have been set in place to ensure that the  
26 procedure is reasonably humane.  
27  
28

1           35. This concern over medically deficient IV placement was demonstrated in three of the  
2 California executions for which records and other information are available. Most recently, during  
3 the execution of Stanley "Tookie" Williams, the injection team took 12 minutes to insert the IV lines.  
4 The first line was placed quickly but spurted blood, and the staff struggled for 11 minutes to insert  
5 the second line, having so much difficulty that Williams asked whether they were "doing that right."  
6 *See The Execution of Stanley Tookie Williams*, SFGate.com (Dec. 14, 2005), attached hereto as  
7 Exhibit 8. The difficulty of the challenge presented to the IV team is evidenced by the comment that  
8 "By 12:10 a.m., the medical tech's lips were tight and white and sweat was pooling on her forehead  
9 as she probed Williams' arm." Similarly, the execution log of Donald Beardslee's execution  
10 indicates that the second IV line was inserted with "difficulty," and the time entries indicate that it  
11 took 12 minutes to insert the second line, which is consistent with encountering problems in inserting  
12 the IV. When it proceeds smoothly, placement of a peripheral IV should, in my experience, take on  
13 the order of two minutes or less. In the execution of William Bonin, it took the staff assigned  
14 anywhere between 18 and 27 minutes to fashion the IV lines (the records are unclear as to this point).  
15 This is an unusually long period of time for an experienced and properly trained professional. In the  
16 execution of Stephen Anderson on January 29, 2002, one of the persons who attempted to secure an  
17 IV was unable to do so without causing significant bleeding and the need to remove his gloves.  
18 Again, this indicates that the process is a difficult one and that it is necessary that the persons doing it  
19 are properly trained and experienced. As is widely recognized in the medical community,  
20 administration of intravenous medications and the management of intravenous systems are complex  
21 endeavors. While speculative and not evidence-based, it is my opinion that it is likely that IV  
22 placement is rendered more difficult in the context of executions because the inmates are often in a  
23 very anxious status, which causes the release of epinephrine (adrenalin) and norepinephrine, thereby  
24 causing constriction (narrowing) of blood vessels (including veins). When veins are  
25 constricted/narrowed it can be difficult or impossible to insert an IV catheter. This is the best  
26  
27  
28

1 explanation I can provide for the otherwise unexplained extremely high incidence of difficult or  
2 failed peripheral IV placement, in individuals lacking known risk factors for difficult IV access, in  
3 Californian and other states during lethal injection.

4 36. It is my further opinion that to ensure a lethal injection without substantial risks of  
5 inflicting severe pain and suffering, there must be proper procedures that are clear and consistent:  
6 there must be qualified personnel to ensure that anesthesia has been achieved prior to the  
7 administration of pancuronium bromide and potassium chloride, there must be qualified personnel to  
8 select chemicals and dosages, set up and load the syringes, administer "pre-injections," insert the IV  
9 catheter, and perform the other tasks required by such procedures; and there must be adequate  
10 inspection and testing of the equipment and apparatus by qualified personnel. The California  
11 Department of Correction's written procedures for implementing lethal injection, to the extent that  
12 they have been made available, provide for none of the above.

14 **C. The Use of Pancuronium Bromide**

15 37. Procedure No. 770's use of the drug pancuronium bromide serves no rational or  
16 legitimate purpose and compounds the risk that an inmate may suffer excruciating pain during his  
17 execution. Pancuronium paralyzes all voluntary muscles, but does not affect sensation,  
18 consciousness, cognition, or the ability to feel pain and suffocation. Because the sodium thiopental  
19 and potassium chloride would in themselves be sufficient to cause death, and the potassium is  
20 administered well before death would result from the pancuronium alone, it is my opinion held to a  
21 reasonable degree of medical certainty that there would be no rational place in the protocol for  
22 pancuronium as the lethal amount of potassium chloride is administered.

24 38. Pancuronium bromide is a neuromuscular blocking agent. Its effect is to render the  
25 muscles unable to contract but it does not affect the brain or the nerves. It is used in surgery to  
26 ensure that there is no movement and that the patient is securely paralyzed so that surgery can be  
27 performed without contraction of the muscles. In surgery, pancuronium bromide is not administered  
28

1 until the patient is adequately anesthetized. The anesthetic drugs must first be administered so that  
2 the patient is unconscious and does not feel, see, or perceive the procedure. This can be determined  
3 by a trained medical professional, either a physician anesthesiologist or a nurse anesthetist, who  
4 provides close and vigilant monitoring of the patient, their vital signs, and various diagnostic  
5 indicators of anesthetic depth. Procedure No. 770, to the extent disclosed, fails to provide an  
6 assurance that anesthetic depth will be properly assessed prior to the administration of pancuronium  
7 bromide.

8  
9 39. If sodium thiopental is not properly administered in a dose sufficient to cause death or  
10 at least the loss of consciousness for the duration of the execution procedure, then it is my opinion  
11 held to a reasonable degree of medical certainty that the use of pancuronium places the condemned  
12 inmate at risk for consciously experiencing paralysis, suffocation and the excruciating pain of the  
13 intravenous injection of high dose potassium chloride.

14 40. If administered alone, a lethal dose of pancuronium would not immediately cause a  
15 condemned inmate to lose consciousness. It would totally immobilize the inmate by paralyzing all  
16 voluntary muscles and the diaphragm, causing the inmate to suffocate to death while experiencing an  
17 intense, conscious desire to inhale. Ultimately, consciousness would be lost, but it would not be lost  
18 as an immediate and direct result of the pancuronium. Rather, the loss of consciousness would be  
19 due to suffocation, and would be preceded by the torment and agony caused by suffocation. This  
20 period of torturous suffocation would be expected to last at least several minutes and would only be  
21 relieved by the onset of suffocation-induced unconsciousness.

22  
23 41. Because the administration of a paralyzing dose of pancuronium bromide to a  
24 conscious person would necessarily cause excruciating suffering, it would be unconscionable to  
25 administer pancuronium without first anesthetizing the inmate.

26 42. Based on the information available to me, it is my opinion held to a reasonable degree  
27 of medical certainty that California's lethal injection protocol creates an unacceptable risk that the  
28

1 inmate will not be anesthetized to the point of being unconscious and unaware of pain for the  
2 duration of the execution procedure. If the inmate is not first successfully anesthetized, then it is my  
3 opinion to a reasonable degree of medical certainty that the pancuronium will paralyze all voluntary  
4 muscles and mask external, physical indications of the excruciating pain being experienced by the  
5 inmate during the process of suffocating (caused by the pancuronium) and having a cardiac arrest  
6 (caused by the potassium chloride).

7  
8 43. It is my understanding that CDC's execution protocol requires the presence of media  
9 witnesses to the execution, and permits the presence of witnesses chosen by the inmate and chosen by  
10 the victim's surviving family members. It is my opinion based on a reasonable degree of medical  
11 certainty that pancuronium, when properly and successfully administered, effectively nullifies the  
12 ability of witnesses to discern whether or not the condemned prisoner is experiencing a peaceful or  
13 agonizing death. Regardless of the experience of the condemned prisoner, whether he or she is  
14 deeply unconscious or experiencing the excruciation of suffocation, paralysis, and potassium  
15 injection, he or she will appear to witnesses to be serene and peaceful due to the relaxation and  
16 immobilization of the facial and other skeletal muscles. The use of pancuronium, in my opinion,  
17 therefore prevents the press from fulfilling its essential function of informing the citizens, officials,  
18 and courts of California about whether execution by lethal injection is conducted in San Quentin  
19 Prisons in a manner that is constitutionally compliant and humane.

20  
21 44. I agree with the statement of the CDC that the doses of sodium thiopental and  
22 potassium chloride are lethal doses. Therefore, it is unnecessary to administer pancuronium bromide  
23 in the course of an execution when it is quickly followed by a lethal dose of potassium chloride. It  
24 serves no legitimate purpose and only places a chemical veil on the process that prevents an adequate  
25 assessment of whether or not the condemned is suffering in agony, and greatly increases the risks that  
26 such agony will ensue. Removal of pancuronium from the protocol would eliminate the risk of  
27 conscious paralysis from occurring. It would also eliminate the risk that an inhumane execution  
28



1 would appear humane to witnesses. Finally, removal of pancuronium would vastly reduce the  
2 possibility that the citizens, officials, and courts of California could be inadvertently misled by media  
3 reports describing a peaceful-appearing execution when in fact the prisoner could be experiencing  
4 excruciating suffering.

5 **D. Consequences of Improper Anesthesia Administration**

6 45. The risk of improper anesthesia administration has been realized in at least one, and  
7 possibly three California executions. The description of the execution of Stephen Anderson set forth  
8 in the Rocconi Declaration suggests that the administration in the bloodstream of five grams of  
9 sodium thiopental did not have the desired effect of sedating Mr. Anderson sufficiently, for reasons  
10 that cannot be identified without further information. The "normal" or "typical" reaction to sodium  
11 thiopental administration, as commonly seen in the operating room setting, is that the patient's eyelids  
12 will drop and close, they may yawn or draw one or two deep breaths, they may exhale visibly so that  
13 the cheeks puff out, and then they become motionless. The Rocconi Declaration describes Mr.  
14 Anderson's chest and stomach as heaving for more than 30 seconds, which does not comport with a  
15 successful administration of a large dose of sodium thiopental. The intermittent and irregular  
16 heaving of the chest is not compatible with the profound depression of the central nervous system  
17 that is the intent of the sodium thiopental administration. The apparent labored respiratory activity  
18 strongly suggests that significant central nervous system activity persisted, and indeed is consistent  
19 with (although does not prove with certainty) the appearance of a person who was struggling against  
20 the development of paralysis induced by pancuronium.

23 46. The administration of a second dose of pancuronium, as indicated in the execution log  
24 of the Bonin execution of February 23, 1996, is a source of great concern. The initial dose of  
25 pancuronium would be expected to paralyze an inmate for several hours. Administration of  
26 additional pancuronium was presumably performed because of some perceived problem or failure of  
27 the first round of drugs, perhaps a concern that the inmate was not anesthetized. If so, it is difficult to  
28

1 understand why additional pancuronium was administered, because pancuronium is not an anesthetic  
2 drug and it would not address this concern. I am aware that the protocols of other states such as  
3 Arizona and Georgia provide for a backup dose of sodium thiopental, which is not part of Procedure  
4 No. 770. The administration of redundant and inappropriate doses of pancuronium raises enormous  
5 concerns about the discipline, logic, medical judgment, and rigor that was applied to the conduct of  
6 this execution.

7  
8 47. The execution of Manuel Babbit also raises grave concerns about whether he was  
9 properly sedated. Although I have not seen any witness accounts of the execution, a review of his  
10 execution log shows that his heart rate maintained a steady rate of between 95 and 96 beats per  
11 minute a full seven minutes after the sodium thiopental was administered to him. If the full five gram  
12 dose of sodium thiopental was properly administered, it is my expectation that there would be  
13 significant hemodynamic consequences including a change of heart rate during this time period.  
14 Such changes in heart rate occurred with the executions of Keith Daniel Williams, Jaturun Siripongs,  
15 and William Bonin in California, according to the logs that I have reviewed. Moreover, the log  
16 indicates that Mr. Babbit had spasmodic movements of the upper chest after the pancuronium  
17 bromide was administered, similar to what was noted during the Stephen Anderson execution, again  
18 raising the concern that Mr. Babbit did not properly receive the full five grams of sodium thiopental  
19 and raises the possibility that he was conscious during the administration of the pancuronium  
20 bromide.  
21

22 **E. Procedure No. 770 Falls Below the Minimum Standards Mandated for Veterinary**  
23 **Euthanasia**

24 48. The injection protocol employed by CDC is strongly discouraged by the American  
25 Veterinary Medical Association (AVMA) and prohibited by law from being used on animals in 19  
26 states. Specifically, the 2000 Report of the Panel on Euthanasia of the American Veterinary Medical  
27  
28

1 Association, at p. 680, states: "A combination of pentobarbital [such as sodium thiopental] with a  
2 neuromuscular blocking agent [such as pancuronium bromide] is not an acceptable euthanasia agent."

3 49. The AVMA Report also states that when potassium chloride is to be used as a  
4 euthanasia agent, the animals must be under a surgical plane of anesthesia and the personnel  
5 performing the euthanasia must be properly trained to assess the depth of anesthesia. The AVMA  
6 panel specifically states that the animal must be in a surgical plane of anesthesia characterized not  
7 simply by loss of consciousness, but also by "loss of reflex muscle response and loss of response to  
8 noxious stimuli." Additionally, the AVMA recommends that sodium pentobarbital be used as an  
9 anesthetic, which is much longer lasting and more stable than sodium thiopental. It is difficult to  
10 understand why the CDC would chose, at its discretion, to use potassium to execute prisoners and  
11 would then fail to adhere to the basic requirements set forth by the AVMA to ensure that animals do  
12 not experience the excruciating pain of potassium injection during euthanasia.

13 50. The AVMA Report also prohibits any use of neuromuscular blocking agents as  
14 euthanizing agents, for precisely the reasons outlined above. Veterinary standards forbid creating the  
15 risk that household pets would die while pancuronium masks the type of excruciating pain risked by  
16 CDC's execution protocol. The use of pancuronium fails to comport with even the minimum  
17 "standard of decency" regarding the euthanasia of household pets. In my medical opinion, based on  
18 a reasonable degree of medical certainty, the use of pancuronium in the lethal injection protocol for  
19 executing human beings violates standards of decency designed to prevent the infliction of  
20 excruciating pain and suffering on human beings.

21 51. Nineteen states have enacted statutes that, like the AVMA Report, "mandate the  
22 exclusive use of a sedative or expressly prohibit the use of a neuromuscular blocking agent in the  
23 euthanasia of animals." See *Beardslee v. Woodford*, 395 F.3d 1064, 1070 & n.9 (9th Cir. 2005)  
24 (citing state laws). Although California has not yet enacted such a statute, the California Code of  
25 Regulations require that personnel who perform euthanasia of animals must be properly trained by  
26  
27  
28

1 veterinarians or registered veterinary nurses in the procedure. No such requirement exists in  
2 Procedure No. 770.

3 **F. Deficiencies in Dr. Dershwitz's Opinions**

4 52. In *Beardslee v. Woodford*, 395 F.3d at 1075, the Ninth Circuit relied in part on the  
5 statements of the defendants' expert, Mark Dershwitz, M.D., Ph.D., in characterizing the key issue in  
6 that case as whether a 5-gram dose of sodium thiopental would be sufficient to render an inmate  
7 unconscious. That characterization misses the point, which is not that the specified quantity of  
8 sodium thiopental is inadequate, but rather that there has been a failure to take all reasonable and  
9 easily taken steps to ensure that the full intended dose of sodium thiopental will in fact be delivered  
10 into the prisoner's circulation. Further, in view of the failure to take all such steps, the particular  
11 selection of an ultra-short acting barbiturate and a paralytic agent needlessly exposes the prisoner to  
12 an increased risk of being inadequately anesthetized.  
13

14 53. I have reviewed the affidavits that Dr. Dershwitz has filed in other lethal injection  
15 challenges, including *Kevin Cooper v. Woodford*, No. C 04 436 JF, *Perkins v. Polk, et. al*, No. 5:04-  
16 CT-643-BO. Those affidavits are attached as Exhibits 4 and 7, respectively. He states that  
17 approximately 99.999999999% of the population would be anesthetized by the full dose of sodium  
18 thiopental, and that successful delivery into the circulation this dose of sodium thiopental would  
19 rapidly render an inmate unconscious, and that unconsciousness would persist well beyond the time  
20 that death would occur. Dr. Dershwitz, however, does not provide any calculations for what would  
21 occur if an error occurred and an insufficient dose of sodium thiopental were to be delivered. None  
22 of his affidavits address the probability of error in the administration of sodium thiopental during the  
23 execution process, or the reality that such errors are more likely to occur in the hands of personnel  
24 who are not trained anesthesiologists or CRNAs.  
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**Conclusion**

54. Based on my research into methods of lethal injection used by various states and the federal government, and based on my training and experience as a medical doctor specializing in anesthesiology, it is my opinion based on a reasonable degree of medical certainty that, given the apparent absence of a central role for a properly trained medical or veterinary professional in CDC's execution procedure, the chemicals used, the lack of adequately defined roles and procedures, and the failure to properly account for foreseeable risks, the lethal injection procedure California employs creates medically unacceptable risks of inflicting excruciating pain and suffering on inmates during the lethal injection procedure. All of these problems could easily be addressed, and indeed have been addressed for the euthanasia of dogs and cats. It is difficult to understand why the CDC has failed to address these problems and has failed to meet the minimum standards set forth for veterinary euthanasia.

55. In addition, in order to more fully and fairly assess the impact of Procedure No. 770's failings, it is necessary to obtain all the records and logs used, and all official witness statements from prior executions, as well as the full rules and regulations devised by CDC for lethal injection. This would include identifying the qualifications, experience and training of those persons who apply the IVs and who administer and monitor the injection.

I declare under penalty of perjury under the laws of the state of California and the United States of America that the foregoing is true and correct. Executed this 12th day of January, 2006 in New York City, New York.

By: 

Dr. Mark Heath

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STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

CALIFORNIA STATE PRISON  
SAN QUENTIN, CALIFORNIA

## LETHAL INJECTION - EXECUTION RECORD

No. C-82702 Name Boardslee Age 48  
 Date Received \_\_\_\_\_ Date Executed \_\_\_\_\_  
 Doctors \_\_\_\_\_

OPERATION	TIME	RATE		REMARKS
		HEART	RES.	
Injection Drugs on Hand <i>11:55 AM</i>	1200		16	
Prisoner Entered Chamber	1205		24	
Saline Solution IV Set and Running <i>(1)</i>	1202		20	<i>0.5 mg/kg 1214 @ 0.5 mg/kg</i>
Chamber Door Locked	1217			
Drug - Sodium Pentothal Started	1218		20	
Drug - Pancuronium Bromide Started	1222			
Drug - Potassium Chloride Started	1225			<i>117 cc from completed 1228</i>
Special Comments				
<i>121st Law FKG</i>	1229			
Respirations Ceased				
Cardiac Monitor - Flatline				
Prisoner Pronounced Dead				
Disposition of Remains:				

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

CALIFORNIA STATE PRISON  
SAN QUENTIN, CALIFORNIA

## LETHAL INJECTION - EXECUTION RECORD

No. C-44650 Name BONIN, William G. Age 49  
 Date Received 03-12-82 Date Executed 2/23/96  
 Doctors \_\_\_\_\_

OPERATION	TIME	RATE		REMARKS
		HEART	RESP.	
Injection Drugs on Hand	2300			
Prisoner Entered Chamber	2336			1st minute Tachycardic - hyperpneic
Saline Solution IV Set and Running	2353			21 + 2 min - apnea
Chamber Door Locked	0003	60	24	
Drug - Sodium Pentothal Started	0008	84	22	VARIED PULSE 47 to 81
Drug - Pancuronium Bromide Started	0009	73	0	0010 2nd Pancuronium given
Drug - Potassium Chloride Started	0011		0	Gradual fall in pulse
Special Comments				70 to 60 to 50
				then sudden drop (precipitous)
				in pulse to 20, 10, 1 etc.
				0 (time 0011 to 0013)
				includes flat line with
				two ectopic narrow
				complexes immediately after
				two burst of low
				amplitude in disorganized
				arrhythmias - also
				low amplitude QRS.
Respirations Ceased	0009			
Cardiac Monitor - Flatline	0013			(not high sensitivity)
Prisoner Pronounced Dead	0013			ECG monitor
Disposition of Remains:				See ACP 5/6 up

CDC-226A (Revised 1-96)

E.R. 0106



STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

CALIFORNIA STATE PRISON  
SAN QUENTIN, CALIFORNIA

## LETHAL INJECTION - EXECUTION RECORD

No. C65500 Name JATURUN SIRIPONGS Date Executed 2/9/99  
 Date Received \_\_\_\_\_ Doctor \_\_\_\_\_

OPERATION	TIME	RATE		REMARKS
		HEART	BSP.	
Injection Drugs on Hand	2300			
Prisoner Entered Chamber	2339			
Saline Solution IV Set and Running	2349			
Chamber Door Locked	2356	87	10	
Drug - Sodium Pentothal Started	0004	87	10	
Drug - Pancuronium Bromide Started	0007	100	8	
Drug - Potassium Chloride Started	0011	70	5	
Special Comments				
Respirations Ceased	0009			
Cardiac Monitor - Flatline	0019			KIDNEY RHYTHM @ 0015
Prisoner Pronounced Dead	0019			EKG OK @ 0019 - line 0019
Disposition of Remains:				

CDC-228A (Rev. 1-94)

E.R. 0107

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

CALIFORNIA STATE PRISON  
SAN QUENTIN, CALIFORNIA

## LETHAL INJECTION - EXECUTION RECORD

No. C-03801 Name KEITH DANIEL WILLIAMS Age 48  
 Date Received (Chen 5-2-96) Date Executed 5-3-96  
 Doctors \_\_\_\_\_

PROCEDURE OPERATION	TIME	RATE		REMARKS
		HEART	RESPIR.	
Injection Drugs on Hand	1130			
Prisoner Entered Chamber	1141			
Saline Solution IV Set and Running	1154			2 <sup>nd</sup> IV @ 11:58
Chamber Door Locked	1202	155	20	
Drug - Sodium Pentothal Started	1203	141	20	
Drug - Pancuronium Bromide Started	1204	100	0	
Drug - Potassium Chloride Started	1205	80	0	
Special Comments				PRONOUNCED @ 12:08
<i>EKG Monitor</i>				
<i>1<sup>st</sup> 30 sec - sinus tachycardia to 155-140</i>				
<i>1<sup>st</sup> minute sustained sinus tachy 130-140</i>				
<i>Then gradual slowing + slight ST depression; QRS narrow + steady 14</i>				
<i>Gradual heart rate 120-110-100; T gradual deepening</i>				
<i>ST merging T wave</i>				
<i>Marked Bradycardia with wide QRS (deep S wave) ST &amp; T wave</i>				
Respirations Ceased	1205			
Cardiac Monitor - Flatline	1206			(00 06) EKG flatline
Prisoner Pronounced Dead	1208			(00 08)

Disposition of Remains:

CDC-228A (Revised 1-96)

E.R. 0108

## LETHAL INJECTION - EXECUTION RECORD

No. C50400 Name MANUEL BABBIT Age 5/4/99  
Date Received \_\_\_\_\_ Date Exposed \_\_\_\_\_  
Doctors \_\_\_\_\_

[illegible]

CDC-226A (Revised 1-56)

DECLARATION OF MARGO A. ROCCONI

I, Margo A. Rocconi, declare and state as follows:

I have personal knowledge of the following and, if called to testify, I could and would competently testify thereto:

1. I am a deputy federal public defender at the Federal Public Defender's Office in the Central District of California. I represented Stephen Wayne Anderson in federal habeas proceedings challenging his conviction and death sentence.

2. I was a witness to the execution of Stephen Wayne Anderson on January 29, 2002 at San Quentin State Prison in California. At about 11:40 p.m. on January 28, 2002, I was transported to the execution viewing area with two other witnesses. The three of us were the last witnesses to enter the viewing area just before 12:00 a.m. on January 29, 2002. We stood on two steps to the left side of the execution chamber. Shortly thereafter, Stephen Anderson was brought into the execution chamber and strapped down onto the table. His right foot twitched from time to time.

3. A male technician came in to the room with a caddy full of syringes and needles. He tried for quite awhile to insert the needle into a vein in Mr. Anderson's left arm. He was not able to find a vein and Mr. Anderson's arm began to bleed. The technician wiped the blood off with gauze several times. The technician became frustrated, removed his gloves, put them back

*MAR*

on, and started over. During this time, Mr. Anderson looked over at his arm several times to see what was happening. Mr. Anderson attempted to help the technician find a vein by pumping his fist. After what took at least 3 to 4 minutes, the technician successfully inserted the needle in Mr. Anderson's arm and taped it down.

4. The male technician then left the room and a female technician entered. She inserted a needle into Mr. Anderson's right arm in less than one minute.

5. Mr. Anderson's table was then turned and the IV lines were attached to a mechanism in the wall of the execution chamber. At this point, Mr. Anderson lifted his head up several times and looked at the three of us standing on the risers.

6. Mr. Anderson then laid his head back down and waited. Within a minute his eyes closed and his head rolled over slightly. Thereafter, his cheeks began puffing as if air were coming out of his mouth. Within moments after that, Mr. Anderson's chest and stomach area began to heave upward. The convulsions continued with some irregular pauses in between. Altogether, Mr. Anderson's chest and stomach heaved more than 30 times.

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7. More than 10 and less than 15 minutes elapsed from the time that Mr. Anderson had closed his eyes until the guard announced that he was dead. I never looked away during that time period.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct.

EXECUTED this 28<sup>th</sup> day of January, 2004.

  
Margo A. Rocconi

DECLARATION OF MARK DERSHWITZ, M.D., Ph.D.

I, Mark Dershwitz, M.D., Ph.D., hereby declare as follows:

1. I am a physician and also have a Ph.D. in pharmacology. A true and accurate copy of my curriculum vitae is attached as Exhibit A. I am licensed to practice medicine in the states of Massachusetts and Maine. I am currently an anesthesiologist at the University of Massachusetts and I am certified by the American Board of Anesthesiology. I am currently Professor of Anesthesiology and Biochemistry and Molecular Pharmacology at the University of Massachusetts.

2. I have done extensive research and written numerous review articles and research papers on the use of anesthetics and I regularly practice medicine in that capacity. My research includes the study of the pharmacodynamics and the pharmacokinetics of drugs. Pharmacokinetics is the study of the time course of a drug, while pharmacodynamics refers to the effects of a drug.

3. Prior to my current appointment at the University of Massachusetts, I have been an Instructor, Assistant Professor and Associate Professor at Harvard Medical School. I have testified as an expert witness concerning the pharmacokinetics and/or pharmacodynamics of anesthetic medications and other medications. I have testified in court as an expert witness on seven occasions. I have given eleven depositions as an expert witness.

4. I have been requested by the California Attorney General's Office to render an expert opinion concerning the effects of administering thiopental sodium, pancuronium bromide and potassium chloride with respect to California's procedures for executing prisoners by lethal injection. While California's execution protocol references "Sodium Pentothal," it is the same substance as thiopental sodium. Accordingly, all discussion in my declaration relating to thiopental sodium references the anesthetic drug being used by California in its execution protocol. I understand that California uses the following procedures for administering thiopental sodium and other drugs before the execution of condemned prisoners:

The syringes containing the drugs are prepared and loaded prior to the inmate being moved into the chamber. The drugs are prepared and loaded in the following order: (a) Two

1 syringes, each containing 20 mL of sterile normal saline, with the syringes being labeled "NS";  
2 (b) Three syringes, each containing 50 mEq of potassium chloride in 25 mL, with the syringes  
3 being labeled "3"; (c) Three syringes each containing 50 mg of pancuronium bromide (Pavulon)  
4 in 50 mL, with the syringes being labeled "2"; (d) four syringes each containing 1.25 grams of  
5 thiopental sodium in a volume of 50 mL. The thiopental sodium, being a federally controlled  
6 drug, shall be prepared last, when it appears that it shall actually be used. These syringes are  
7 labeled "1". Pre-medication with Valium, or its equivalent, is available to the inmate if  
8 requested and approved by the Health Care Manager. It is noted that three syringes of  
9 pancuronium bromide and potassium chloride are prepared, with two being used, and one extra  
10 of each prepared as "stand-bys" in the event one is dropped in handling during the injection  
11 procedure.

12 A primary injection site is established by means of an intravenous catheter inserted into a  
13 usable vein, and an infusion of normal saline solution is thereby initiated. A second infusion of  
14 normal saline solution is likewise established at a secondary site, to be used in the event that  
15 blockage or malfunction occurs at the primary site. The first chemical administered is 5 grams  
16 of thiopental sodium, which is immediately followed by a saline flush. The second chemical is  
17 100 mg of pancuronium bromide, and it is also followed immediately by a saline flush. The  
18 third chemical is 100 mEq of potassium chloride. The chemicals are administered successively,  
19 in the order listed, with the second chemical introduced immediately after injection of the first  
20 chemical and saline flush is completed, and the third chemical introduced immediately after  
21 injection of the second chemical and saline flush is completed.

22 5. I have performed a detailed pharmacokinetic and pharmacodynamic analysis of  
23 the effects of a 5-gram dose of thiopental sodium given to an average man with a mass of 80  
24 kilograms or about 176 pounds. It is my opinion, to a reasonable degree of medical certainty,  
25 that a condemned inmate who is administered five grams of thiopental sodium will be rendered  
26 unconscious, and not experience pain for the time period necessary to complete the execution.  
27 The following discussion will quantitate the miniscule probability that the person could be  
28 conscious during the period of time that elapses between the administration of thiopental sodium



1 and the person's death. Even in persons of greater size or with inherent drug tolerance (due, for  
2 example, to the prior administration of therapeutic medications) the listed probabilities would not  
3 be altered in a meaningful way.

4 6. From my pharmacokinetic analysis I have generated a graph, attached as Exhibit  
5 B. This pharmacokinetic graph shows the concentration of thiopental in the blood in an average  
6 man as a function of time. In Exhibit B, the time course considered is two hundred minutes. In  
7 Exhibit B, the y-axis is the concentration of thiopental in blood measured in mcg/mL  
8 (micrograms or millionths of a gram per milliliter). As shown in Exhibit B, after the  
9 administration of five grams of thiopental sodium, the blood concentration of thiopental would  
10 be about 240 mcg/mL about one minute after the injection begins, falling to about 56.8 mcg/mL  
11 after 20 minutes and to about 13.5 mcg/mL after 200 minutes. It should be noted that twenty  
12 minutes is more than twice as long as any prior execution in California has required using the  
13 procedure described herein. The blood concentration of thiopental at which 50% of people are  
14 conscious and 50% are unconscious is 7 mcg/mL; about 820 minutes must elapse until this point  
15 is reached.

16 7. From my pharmacodynamic analysis, I have generated a graph, attached as  
17 Exhibit C. This pharmacodynamic graph shows the probability that an average man will be  
18 conscious as a function of the blood concentration of thiopental. In other words, the graph shows  
19 the likelihood of consciousness in the presence of varying blood concentrations of thiopental.  
20 The graph shows that it is extraordinarily unlikely that someone will remain conscious during the  
21 hour following the administration of five grams of thiopental.

22 8. It is my opinion to a reasonable degree of medical certainty that thiopental sodium  
23 given as described above would render most people unconscious within sixty seconds from the  
24 time of the start of administration. By the time all 200 mL of thiopental sodium solution are  
25 injected, it is my further opinion, to a reasonable degree of medical certainty, that over  
26 99.999999999999% of the population would be unconscious. Furthermore, this dose of  
27 thiopental sodium will cause virtually all persons to stop breathing within a minute of drug  
28 administration. Thus, although the subsequent administration of pancuronium bromide, a

1 paralytic agent, would have the effect of paralyzing the person and preventing him from being  
2 able to breathe, virtually every person given five grams of thiopental sodium will have stopped  
3 breathing prior to the administration of pancuronium bromide. Thus, even in the absence of the  
4 administration of pancuronium bromide and potassium chloride, the administration of five grams  
5 of thiopental sodium by itself would be lethal in almost everyone.

6 9. It is my opinion, to a reasonable degree of medical certainty, that there is  
7 approximately a 0.00000006% probability that a condemned inmate given this dose would be  
8 conscious, and able to experience pain, after a period of five minutes.

9 10. It is my opinion, to a reasonable degree of medical certainty, that there is  
10 approximately a 0.0000015% probability that a condemned inmate given this dose would be  
11 conscious, and able to experience pain after a period of ten minutes.

12 11. It is my opinion, to a reasonable degree of medical certainty, that there is  
13 approximately a 0.000021% probability that a condemned inmate given this dose would be  
14 conscious, and able to experience pain after a period of 30 minutes.

15 12. It is my opinion, to a reasonable degree of medical certainty, that there is  
16 approximately a 0.011% probability that a condemned inmate given this dose would be  
17 conscious, and able to experience pain, after a period of 100 minutes.

18 13. Finally, it is my opinion, based upon a reasonable degree of medical certainty, the  
19 administration of five grams of thiopental sodium would render most people unconscious for a  
20 period of in excess of 13 hours.

21 14. Therefore, it is my opinion to a reasonable degree of medical certainty that there  
22 is an exceedingly small risk that a condemned inmate under these circumstances would  
23 experience any pain associated with the infusion of lethal doses of pancuronium bromide and  
24 potassium chloride.

25 15. I have reviewed the declaration of Dr. Mark Heath, filed in the Federal Court in  
26 California regarding condemned inmate Kevin Cooper. I note that Dr. Heath's published works  
27 focus on the molecular mechanisms of pain. It does not appear that Dr. Heath has particular  
28 expertise with respect to the pharmacodynamics and pharmacokinetics of anesthetic medications.

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1 In other words, Dr. Heath has no apparent expertise in the time course of a medication's effect,  
2 which in my view is the primary medical and scientific issue raised in this case. While all  
3 anesthesiologists should be familiar with the use of thiopental sodium, pancuronium bromide and  
4 potassium chloride, my primary research interest throughout my career in anesthesiology has  
5 been the study of the time course of the effects of anesthetic medications.

6 16. I have reviewed the declaration of Dr. Corey Weinstein filed in the Federal Court  
7 in California regarding condemned inmate Kevin Cooper. Dr. Weinstein appears to practice  
8 internal medicine, and nothing indicates any particular expertise relating to anesthesiology. Dr.  
9 Weinstein offers opinions that are similar to those expressed by Dr. Heath, and accordingly, my  
10 discussion regarding why Dr. Heath's opinions are scientifically erroneous apply equally to Dr.  
11 Weinstein's opinions.

12 17. Paragraph 21 of Dr. Heath's declaration states that "[a]s with most drugs, a  
13 person's body composition (size, weight, and drug tolerance), and any medications they may  
14 have taken, cause the inmate to react differently to the chemicals. Thus, some prisoners may  
15 need a higher concentration of sodium pentothal than others before losing consciousness.  
16 California's failure to account for each inmate's physiological attributes increases the probability  
17 that the inmate will not be unconscious when the other chemicals are administered causing the  
18 inmate to suffer an excruciatingly painful death." It is my opinion, to a reasonable degree of  
19 medical certainty, that a 5-gram dose of thiopental sodium administered as described above is a  
20 dose sufficient to induce unconsciousness for a period well in excess of the time necessary to  
21 complete an execution. When thiopental sodium is commonly used for general anesthesia in  
22 surgery, it is normally administered in a dose of 300 to 400 milligrams. Five grams, the amount  
23 of thiopental sodium used in California's executions, is at least 12.5 times the commonly used  
24 surgical dosage.

25 18. Paragraph 23 of Dr. Heath's declaration states that the "failure to require a  
26 continuous infusion of sodium pentothal places the condemned inmate at a needless and  
27 significant risk for the conscious experience of paralysis during the excruciating pain of both  
28 suffocation and the intravenous injection of potassium chloride." This statement is scientifically

1 erroneous. It is my opinion, to a reasonable degree of medical certainty, that continuous infusion  
2 would not significantly decrease the already exceedingly small risk that a condemned inmate  
3 would regain consciousness. In fact, the difference between the procedure outlined above for  
4 administering thiopental sodium versus a continuous infusion of 500 milligrams per minute for  
5 ten minutes is negligible.

6 19. Paragraph 15 of Dr. Heath's declaration states that pancuronium bromide, as used  
7 in executions, "nullifies the ability of witnesses to discern whether or not the condemned  
8 prisoner is experiencing a peaceful or agonizing death." This statement is scientifically  
9 erroneous. The inmate would not experience any pain or discomfort because he has been  
10 rendered unconscious by thiopental sodium. Pancuronium bromide acts to stop an inmate's  
11 breathing. It would also act to prevent the manifestations of seizure activity. Such seizures  
12 occur commonly after a person's heart stops beating. Thus, the absence of pancuronium bromide  
13 may be erroneously interpreted by the lay observer as pain or discomfort. In my opinion, to a  
14 reasonable degree of medical certainty, California's use of thiopental sodium before, and in  
15 combination with, pancuronium bromide and potassium chloride, results in an inmate's rapid and  
16 painless death.

17 20. Paragraph 18 of Dr. Heath's declaration states that thiopental sodium has a very  
18 "short shelf life in liquid form," and therefore, this results in a "major concern" relating to its  
19 use. It is my opinion, to a reasonable degree of medical certainty, that preparation of a 2.5%  
20 solution of thiopental sodium within one hour of its use presents no concern as to its stability and  
21 effectiveness when used. It is my further opinion that such a concentration should remain stable  
22 in liquid form for at least twenty-four hours at room temperature after preparation.

23 21. I am informed that California uses licensed registered or vocational nurses to  
24 prepare and insert the intravenous catheters. It is my opinion, to a reasonable degree of medical  
25  
26  
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28

1 certainty, that registered or vocational nurses licensed by California would be competent to  
2 prepare and insert such intravenous catheters.

3 Executed under penalty of perjury under the laws of the United States, on this third day  
4 of February, 2004, at Worcester, Massachusetts.

5  
6 Dated: 3 February 2004

  
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MARK DERSHWITZ, M.D., Ph.D.

# 2000 Report of the AVMA Panel on Euthanasia



**Advantages**—(1) Potassium chloride is not a controlled substance. It is easily acquired, transported, and mixed in the field. (2) Potassium chloride, when used with appropriate methods to render an animal unconscious, results in a carcass that is potentially less toxic for scavengers and predators in cases where carcass disposal is impossible or impractical.

**Disadvantage**—Rippling of muscle tissue and clonic spasms may occur on or shortly after injection.

**Recommendations**—It is of utmost importance that personnel performing this technique are trained and knowledgeable in anesthetic techniques, and are competent in assessing anesthetic depth appropriate for administration of potassium chloride intravenously. Administration of potassium chloride intravenously requires animals to be in a surgical plane of anesthesia characterized by loss of consciousness, loss of reflex muscle response, and loss of response to noxious stimuli. Saturated potassium chloride solutions are effective in causing cardiac arrest following rapid intracardiac or intravenous injection. Residual tissue concentrations of general anesthetics after anesthetic induction have not been documented. Whereas no scavenger toxicoses have been reported with potassium chloride in combination with a general anesthetic, proper carcass disposal should always be attempted to prevent possible toxicosis by consumption of a carcass contaminated with general anesthetics.

#### **Unacceptable injectable agents**

When used alone, the injectable agents listed in Appendix 4 (strychnine, nicotine, caffeine, magnesium sulfate, potassium chloride, cleaning agents, solvents, disinfectants and other toxins or salts, and all neuromuscular blocking agents) are unacceptable and are absolutely condemned for use as euthanasia agents.

#### **PHYSICAL METHODS**

Physical methods of euthanasia include captive bolt, gunshot, cervical dislocation, decapitation, electrocution, microwave irradiation, kill traps, thoracic compression, exsanguination, stunning, and pithing. When properly used by skilled personnel with well-maintained equipment, physical methods of euthanasia may result in less fear and anxiety and be more rapid, painless, humane, and practical than other forms of euthanasia. Exsanguination, stunning, and pithing are not recommended as a sole means of euthanasia, but should be considered adjuncts to other agents or methods.

Some consider physical methods of euthanasia aesthetically displeasing. There are occasions, however, when what is perceived as aesthetic and what is most humane are in conflict. Physical methods may be the most appropriate method for euthanasia and rapid relief of pain and suffering in certain situations. Personnel performing physical methods of euthanasia must be well trained and monitored for each type of physical technique performed. That person must also be sensitive to the aesthetic implications of the method and inform onlookers about what they should expect when possible.

Since most physical methods involve trauma, there is inherent risk for animals and humans. Extreme care and caution should be used. Skill and experience of personnel is essential. If the method is not performed correctly, animals and personnel may be injured. Inexperienced persons should be trained by experienced persons and should practice on carcasses or anesthetized animals to be euthanatized until they are proficient in performing the method properly and humanely. When done appropriately, the panel considers most physical methods conditionally acceptable for euthanasia.

#### **Penetrating captive bolt**

A penetrating captive bolt is used for euthanasia of ruminants, horses, swine, laboratory rabbits, and dogs.<sup>108</sup> Its mode of action is concussion and trauma to the cerebral hemisphere and brainstem.<sup>109,110</sup> Captive bolt guns are powered by gunpowder or compressed air and must provide sufficient energy to penetrate the skull of the species on which they are being used.<sup>109</sup> Adequate restraint is important to ensure proper placement of the captive bolt. A cerebral hemisphere and the brainstem must be sufficiently disrupted by the projectile to induce sudden loss of consciousness and subsequent death. Accurate placement of captive bolts for various species has been described.<sup>109-112</sup> A multiple projectile has been suggested as a more effective technique, especially for large cattle.<sup>109</sup>

A nonpenetrating captive bolt only stuns animals and should not be used as a sole means of euthanasia (see "Stunning" under "Adjunctive Methods").

**Advantage**—The penetrating captive bolt is an effective method of euthanasia for use in slaughterhouses, in research facilities, and on the farm when use of drugs is inappropriate.

**Disadvantages**—(1) It is aesthetically displeasing. (2) Death may not occur if equipment is not maintained and used properly.

**Recommendations**—Use of the penetrating captive bolt is an acceptable and practical method of euthanasia for horses, ruminants, and swine. It is conditionally acceptable in other appropriate species. The nonpenetrating captive bolt must not be used as a sole method of euthanasia.

#### **Euthanasia by a blow to the head**

Euthanasia by a blow to the head must be evaluated in terms of the anatomic features of the species on which it is to be performed. A blow to the head can be a humane method of euthanasia for neonatal animals with thin craniums, such as young pigs, if a single sharp blow delivered to the central skull bones with sufficient force can produce immediate depression of the central nervous system and destruction of brain tissue. When properly performed, loss of consciousness is rapid. The anatomic features of neonatal calves, however, make a blow to the head in this species unacceptable. Personnel performing euthanasia by use of a blow to the head must be properly trained and monitored for proficiency with this method of euthanasia, and they must be aware of its aesthetic implications.

## **Practice Advisory for Intraoperative Awareness and Brain Function Monitoring**

*A Report by the American Society of Anesthesiologists Task Force on Intraoperative Awareness\**

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys. Advisories are not intended as standards, guidelines, or absolute requirements. They may be adopted, modified, or rejected according to clinical needs and constraints.

The use of practice advisories cannot guarantee any specific outcome. Practice advisories summarize the state of the literature and report opinions derived from a synthesis of task force members, expert consultants, open forums and public commentary. Practice advisories are not supported by scientific literature to the same degree as are standards or guidelines because sufficient numbers of adequately controlled studies are lacking. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

### **Methodology**

#### *A. Definitions*

Intraoperative awareness under general anesthesia is a rare occurrence, with a reported incidence of 0.1-0.2%.<sup>1-4</sup> Significant psychological sequelae (e.g., post traumatic stress disorder) may occur following an episode of intraoperative awareness, and affected patients may remain severely disabled

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\* Developed by the American Society of Anesthesiologists Task Force on Intraoperative Awareness: Jeffrey L. Apfelbaum, M.D., (Chair), Chicago, Illinois; James F. Arens, M.D., Houston, Texas; Daniel J. Cole, M.D., Phoenix, Arizona; Richard T. Connis, Ph.D., Woodinville, Washington; Karen B. Domino, M.D., Seattle, Washington; John C. Drummond, M.D., San Diego, California; Cor J. Kalkman, M.D., Ph.D., Utrecht, the Netherlands; Ronald D. Miller, M.D., San Francisco, California; David G. Nickinovich, Ph.D., Bellevue, Washington; and Michael M. Todd, M.D., Iowa City, Iowa.

Supported by the American Society of Anesthesiologists under the direction of James F. Arens, M.D., Chair, Committee on Practice Parameters. A list of the references used to develop this Advisory is available by writing to the American Society of Anesthesiologists.

Address reprint requests to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573



The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology*.

for extended periods of time.<sup>5</sup> However, in some circumstances, intraoperative awareness may be unavoidable in order to achieve other critically important anesthetic goals.

The following terms or concepts discussed in this Advisory include: consciousness, general anesthesia, depth of anesthesia or depth of hypnosis, recall, amnesia, intraoperative awareness, and brain function monitors. Consistent definitions for these terms are not available in the literature. For purposes of this Advisory, these terms are operationally defined or identified as follows:

- (1) Consciousness: Consciousness is a state in which a patient is able to process information from his or her surroundings. Consciousness is assessed by observing a patient's purposeful responses to various stimuli. Identifiers of purposeful responses include organized movements following voice commands or noxious/painful stimuli.<sup>†</sup> For example, opening of the eyes is one of several possible identifiers or markers of consciousness. Purposeful responses may be absent when paralysis is present as a consequence of neurological disease or the administration of a neuromuscular blocking drug.
- (2) General anesthesia: General anesthesia is defined as a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation.<sup>‡</sup> The ability to maintain ventilatory function independently is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
- (3) Depth of anesthesia: Depth of anesthesia or depth of hypnosis refers to a continuum of progressive central nervous system depression and decreased responsiveness to stimulation.

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<sup>†</sup> Reflex withdrawal from a painful stimulus is NOT considered a purposeful response, as indicated by the "continuum of depth of sedation, definition of general anesthesia, and levels of sedation/analgesia;" American Society of Anesthesiologists, 2004.

<sup>‡</sup> American Society of Anesthesiologists: Continuum of depth of sedation, definition of general anesthesia, and levels of sedation/analgesia;" ASA Standards, Guidelines and Statements, 2004.

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology*.

- (4) Recall: For the purpose of this Advisory, recall is the patient's ability to retrieve stored memories. Recall is assessed by a patient's report of previous events, in particular, events that occurred during general anesthesia. *Explicit memory* is assessed by the patient's ability to recall specific events that took place during general anesthesia. *Implicit memory* is assessed by changes in performance or behavior without the ability to recall specific events that took place during general anesthesia that led to those changes.<sup>6</sup> A report of recall may be spontaneous or it may only be elicited in a structured interview or questionnaire. This Advisory does not address implicit memory.
- (5) Amnesia: Amnesia is the absence of recall. Many anesthetic drugs produce amnesia at concentrations well below those necessary for suppression of consciousness. Anterograde amnesia is intended when a drug with amnestic properties is administered before induction of anesthesia. Retrograde amnesia is intended when a drug such as a benzodiazepine is administered after an event that may have caused or been associated with intraoperative consciousness in the hope that it will suppress memory formation and "rescue" from recall.
- (6) Intraoperative awareness: Intraoperative awareness occurs when a patient becomes conscious during a procedure performed under general anesthesia and subsequently has recall of these events. For the purpose of this Advisory, recall is limited to explicit memory, and does not include the time before general anesthesia is fully induced or the time of emergence from general anesthesia, when arousal and return of consciousness are intended. Dreaming is not considered intraoperative awareness.
- (7) Brain function monitors: Brain function monitors are devices that record or process brain electrical activity and convert these signals mathematically into a continuous measure typically scaled from 0 to 100. In addition to spontaneous cortical electrical activity (electroencephalogram, EEG), these devices may also record and process evoked cortical and

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subcortical activity (auditory evoked potentials, or AEP) as well as electromyographic (EMG) activity from scalp muscles. For the purpose of this Advisory, only monitors purported to measure depth of anesthesia or hypnosis will be considered. Other, non-EEG/AEP/EMG devices are also available, but are not addressed by this Advisory.

*B. Purposes of the Advisory*

Intraoperative awareness under general anesthesia is an important clinical problem that clearly is within the foundation of training and continuing medical education in anesthesiology. The purposes of this Advisory are to identify risk factors that may be associated with intraoperative awareness, provide decision tools that may enable the clinician to reduce the frequency of unintended intraoperative awareness, stimulate the pursuit and evaluation of strategies that may prevent or reduce the frequency of intraoperative awareness, and provide guidance for the intraoperative use of brain function monitors as they relate to intraoperative awareness.

*C. Focus*

This Advisory focuses on the perioperative management of patients who are undergoing a procedure during which general anesthesia is administered. This Advisory is not intended for the perioperative management of minimal, moderate, or deep sedation in the OR or ICU; regional or local anesthesia without general anesthesia; monitored anesthesia care; tracheal intubation of patients or those undergoing resuscitation in emergency trauma after the administration of a neuromuscular block, or intentional intraoperative wake-up testing (e.g., for the purposes of assessing intraoperative neurologic function). In addition, this Advisory is not intended to address the perioperative management of pediatric patients.

*D. Application*

This Advisory is intended for use by anesthesiologists, other physicians who supervise the administration of general anesthesia, and all other individuals who administer general anesthesia.

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology*.

The Advisory may also serve as a resource for other physicians and health care professionals who are involved in the perioperative management of patients receiving general anesthesia.

*E. Task Force Members and Consultants*

The American Society of Anesthesiologists (ASA) appointed this Task Force of 10 members to (1) review and assess the currently available scientific literature on intraoperative awareness, (2) obtain expert consensus and public opinion, and (3) develop a practice advisory. The Task Force is comprised of anesthesiologists from various geographic areas of the United States, an anesthesiologist from the Netherlands, and two methodologists from the ASA Committee on Practice Parameters.

The ASA appointed the 10 members to the Task Force because of their knowledge or expertise in the medical specialty of anesthesiology, and the development of practice parameters. The members include but are not limited to anesthesiologists with specialized knowledge or expertise in the area of neuroanesthesiology. Two of the 10 members disclosed receipt of funds from or a financial interest in a company developing or manufacturing brain function monitors, which companies have a direct financial interest in the expanded use of such monitors. Other members may have received funds from or have a financial interest in other companies, such as developers or manufacturers of anesthetics, that may be indirectly affected by the expanded use of brain function monitors. The Task Force did not request its members to disclose such interests because they were deemed too remote and speculative to present conflicts of interest.

The Task Force, in turn, sought input from consultants, many of whom who had particularized knowledge, expertise and/or interest in intraoperative awareness and brain function monitors. Such knowledge or expertise is based in part in some cases on research or investigational activities funded by a company developing or manufacturing brain function monitors. Fifty-four percent of the consultants disclosed receipt of funds from or a financial interest in a company developing or

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manufacturing brain function monitors. Consultants also may have received funds from or have a financial interest in other companies that may be indirectly affected by the use of brain function monitors. The Task Force did not request its consultants to disclose such interests because they were deemed too remote and speculative to present conflicts of interest.

The Task Force used a six-step process. First, the members reached consensus on the criteria for evidence of effective perioperative interventions for the prevention of intraoperative awareness. Second, they evaluated original articles published in peer-reviewed journals relevant to this issue. Third, consultants who had expertise or interest in intraoperative awareness and who practiced or worked in diverse settings (e.g., scientists and/or physicians in academic and private practice) were asked to participate in opinion surveys on the effectiveness of various perioperative management strategies, and to review and comment on a draft of the Advisory developed by the Task Force. Fourth, additional opinions were solicited from a random sample of active members of the ASA. Fifth, the Task Force held open forums at three national and international anesthesia meetings to solicit input on the key concepts of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

The draft document was made available for review on the ASA website, and commentary was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

#### *F. Availability and Strength of Evidence*

Practice advisories are developed by a protocol similar to that of an ASA evidence-based practice guideline, including a systematic search and evaluation of the literature. However, practice advisories lack the support of a sufficient number of adequately controlled studies to permit aggregate analyses of data with rigorous statistical techniques such as meta-analysis. Nonetheless, literature-based evidence from case reports and other descriptive studies are considered during the

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development of the Advisory. This literature often permits the identification of recurring patterns of clinical practice.

As with a practice guideline, formal survey information is collected from consultants and members of the ASA. The following terms describe survey responses for any specified issue. Responses are solicited on a 5-point scale; ranging from 1 (strongly disagree) to 5 (strongly agree) with a score of 3 being equivocal. Survey responses are summarized based on median values as follows:

<u>Strongly Agree:</u>	Median score of 5 (At least 50% of the responses are 5)
<u>Agree:</u>	Median score of 4 (At least 50% of the responses are 4 or 4 and 5)
<u>Equivocal:</u>	Median score of 3 (At least 50% of the responses are 3, or no other response category or combination of similar categories contain at least 50% of the responses)
<u>Disagree:</u>	Median score of 2 (At least 50% of responses are 2 or 1 and 2)
<u>Strongly Disagree:</u>	Median score of 1 (At least 50% of responses are 1)

Additional information is obtained from open forum presentations and other invited and public sources. The advisory statements contained in this document represent a distillation of the current spectrum of clinical opinion and literature-based findings.<sup>§</sup>

## **Advisories**

### *I. Preoperative Evaluation*

A preoperative evaluation includes (1) obtaining a focused history (i.e., medical records, laboratory reports, patient or patient and family interview), (2) conducting a physical examination, (3) identifying patients at risk for intraoperative awareness (e.g., planned anesthetics, type of surgery), and (4) informing selected patients of the possibility of intraoperative awareness.

Descriptive studies and case reports suggest that certain patient characteristics may be associated with intraoperative awareness, including age, gender, ASA status, and drug resistance or tolerance.<sup>4,7-</sup>

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<sup>§</sup> Refer to appendix 1 for a summary of the advisories.

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<sup>11</sup> Descriptive studies and case reports suggest that certain procedures (e.g., cesarean section, cardiac surgery, trauma surgery)<sup>4,8,12-29</sup> as well as anesthetic techniques (e.g., rapid-sequence induction, reduced anesthetic doses with or without the presence of paralysis)<sup>2,3,9,13,16,21,23,30-33</sup> may be associated with an increased risk of intraoperative awareness. No studies were found that examined the clinical impact of informing the patient prior to surgery of the possibility of intraoperative awareness.

The consultants and ASA members agree that a preoperative evaluation may be helpful in identifying patients at risk for intraoperative awareness.<sup>\*\*</sup> In addition, they agree that a focused preoperative evaluation to identify patients at risk of intraoperative awareness should include review of a patient's medical record, a thorough physical examination, and a patient or patient and family interview. They agree that patient characteristics that may place a patient at risk for intraoperative awareness include: substance use or abuse, limited hemodynamic reserve, and ASA status of 4 or 5. The consultants strongly agree and the ASA members agree that a history of intraoperative awareness may place a patient at risk. The consultants disagree and the ASA members are equivocal regarding whether all patients should be informed of the possibility of intraoperative awareness. The consultants strongly agree and the ASA members agree that only patients considered to be at elevated risk of intraoperative awareness should be informed of the possibility of intraoperative awareness. Finally the consultants and the ASA members disagree that informing the patient preoperatively of the risk of intraoperative awareness increases the *actual* risk of intraoperative awareness.

**Advisory.** The Task Force believes that some components of the preoperative evaluation may be useful in identifying a patient at increased risk for awareness. An evaluation should include, if possible, a review of a patient's medical records for previous occurrences of awareness or other potential risk factors, a patient interview to assess level of anxiety or previous experiences with anesthesia, and a physical examination. Potential risk factors to consider for patients undergoing

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<sup>\*\*</sup> Refer to appendix 2 for complete results of the consultant and ASA membership surveys.

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general anesthesia include substance use or abuse (e.g., opioids, benzodiazepines, cocaine), a history of awareness, a history of difficult intubation or anticipated difficult intubation, chronic pain patients on high doses of opioids, cardiac surgery, Cesarean section, trauma and emergency surgery, reduced anesthetic doses in the presence of paralysis, planned use of muscle relaxants during the maintenance phase of general anesthesia, total intravenous anesthesia, the planned use of nitrous oxide-opioid anesthesia, ASA status of 4 or 5, and limited hemodynamic reserve. The consensus of the Task Force is that patients whom the individual clinician considers to be at substantially increased risk of intraoperative awareness should be informed of the possibility of intraoperative awareness when circumstances permit.

## *II. Preinduction Phase of Anesthesia*

Issues concerned with the preinduction phase of anesthesia related to the prevention of intraoperative awareness include checking the functioning of anesthesia delivery systems, and the prophylactic administration of benzodiazepines.

Although checking the functioning of anesthesia delivery systems is standard practice, some cases of intraoperative awareness have resulted from too low concentrations of inspired volatile anesthetics or drug errors, including drug delivery errors.<sup>8,34-39</sup> One double-blind randomized clinical trial evaluated the efficacy of the prophylactic administration of midazolam as an anesthetic adjuvant during ambulatory procedures under total intravenous anesthesia and reported a lower frequency of intraoperative awareness in the midazolam groups compared to the placebo group.<sup>40</sup> Two randomized clinical trials examined anterograde amnesia by providing pictures as stimuli after administration of midazolam but before induction of general anesthesia. Although these studies reported reduced recall in patients administered midazolam, the presence of consciousness during general anesthesia and subsequent intraoperative awareness was not examined.<sup>41,42</sup>



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The consultants and ASA members strongly agree that the functioning of anesthesia delivery systems (e.g., vaporizers, infusion pumps, fresh gas flow, IV lines) should be checked to reduce the risk of intraoperative awareness. The consultants disagree, and the ASA members are equivocal that a benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraoperative awareness for *all* patients. The consultants agree that a benzodiazepine or scopolamine should be used for patients requiring smaller dosages of anesthetics, patients undergoing cardiac surgery, and patients undergoing trauma surgery. They are equivocal regarding patients undergoing Cesarean section, emergency surgery, and with total intravenous anesthesia. The ASA members agree that a benzodiazepine or scopolamine should be used for patients requiring smaller dosages of anesthetics, patients undergoing cardiac surgery, emergency surgery, trauma surgery, and total intravenous anesthesia. They are equivocal regarding patients undergoing Cesarean section.

**Advisory.** Since intraoperative awareness may be caused by equipment malfunction or misuse, the Task Force believes that there should be adherence to a checklist protocol for anesthesia machines and equipment to assure that the desired anesthetic drugs and doses will be delivered. These procedures should be extended to include verification of the proper functioning of intravenous access, infusion pumps and their connections. The Task Force consensus is that the decision to administer a benzodiazepine prophylactically should be made on a case-by-case basis for selected patients (e.g., patients requiring smaller dosages of anesthetics). The Task Force cautions that delayed emergence may accompany the use of benzodiazepines.

### *III. Intraoperative Monitoring*

Intraoperative awareness cannot be measured during the intraoperative phase of general anesthesia, since the recall component of awareness can only be determined postoperatively by obtaining information directly from the patient. Therefore, the primary issue regarding intraoperative

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monitoring addressed by this Advisory is whether the use of clinical techniques, conventional monitoring systems, or brain function monitors reduce the occurrence of intraoperative awareness.

The majority of literature obtained during the search and review process did not directly address whether these techniques, systems, or monitors reduce the frequency of intraoperative awareness. However, many studies were found that report intraoperative measures or index values from monitoring activities. This literature, while not directly assessing the impact of an intervention on awareness, often reported patterns or values that occurred at identifiable times during the perioperative period with the intention of describing or predicting variations in the depth of anesthesia. Therefore, commonly reported findings from this literature are summarized below.

The literature for each intervention is presented in the following order: (1) randomized clinical trials, (2) nonrandomized comparative studies (e.g., quasi-experimental, prospective cohort studies), (3) correlational studies (e.g., correlations of index values with end-tidal concentrations of hypnotic drugs or with movement in response to noxious stimuli), (4) descriptive reports of monitor index values at particular times during a procedure; and (5) case reports of unusual or unintended benefits or harms occurring during a monitoring activity. Correlational studies often report a measure of association between two continuous variables (e.g., the correlation between index values and anesthetic drug concentrations). Other correlational measures include a prediction probability (Pk) value that provides a measure of how well a monitor or technique can differentiate between two different clinical states (e.g., response versus no response to verbal command).<sup>43</sup> A Pk value of 1.0 indicates perfect association between an index value and a clinical state, while a Pk value of 0.50 indicates a prediction probability equal to chance.

#### *A. Clinical Techniques and Conventional Monitoring:*

Among the clinical techniques utilized to assess intraoperative consciousness are checking for movement, response to commands, opened eyes, eyelash reflex, pupillary responses or diameters,

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perspiration and tearing. Conventional monitoring systems include ASA standard monitoring<sup>††</sup> as well as the end-tidal anesthetic analyzer.

No clinical trials or other comparative studies were found that examine the effect of clinical techniques or conventional monitoring on the incidence of intraoperative awareness. Correlational studies reported Pk values ranging from 0.74 to 0.76 for the association between reflex or purposeful movement and indicators for depth of anesthesia.<sup>44</sup> One study reported a significant association between response to command and memory when continuous infusions of propofol were used as the induction anesthetic.<sup>45</sup> Pk values for mean arterial pressure (MAP) ranged from 0.68 to 0.94 for distinguishing a responsive state from an unresponsive state, and from 0.81 to 0.89 for distinguishing an anesthetized state from emergence following anesthesia (i.e., first response). Pk values for heart rate (HR) ranged from 0.50 to 0.82 for distinguishing a responsive state from an unresponsive state, and from 0.54 to 0.67 for emergence.<sup>46-48</sup> Wide ranges of mean MAP and HR values were reported during various intraoperative times. Studies reported ranges of mean MAP values as follows: before induction or baseline, 90 to 103 mmHg; at induction, 58.4 to 88 mmHg; during surgery, 78 to 102 mmHg; at emergence or end of surgery, 58.7 to 97 mmHg; and during postoperative recovery, 86 to 104mmHg. Mean HR ranges were reported as follows: before induction or baseline, 61 to 82 bpm; at induction, 55 to 67 bpm; during surgery, 74 to 82 bpm; at emergence or end of surgery, 59 to 92 bpm; and during postoperative recovery, 82 to 89 bpm.<sup>49-56</sup> Awareness has been reported to occur in the absence of tachycardia or hypertension.<sup>8,23,24</sup>

The consultants and ASA members agree that clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to assess intraoperative consciousness. In addition, the consultants and ASA members agree that conventional monitoring systems (e.g, ECG,

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<sup>††</sup> American Society of Anesthesiologists: Standards for basic anesthetic monitoring. *In* ASA Standards, Guidelines and Statements; American Society of Anesthesiologists Publication: October, 2004.

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BP, HR, end-tidal anesthetic analyzer, capnography) are valuable and should be used to help assess intraoperative consciousness.

*B. Brain Electrical Activity Monitoring:*

Most of the devices designed to monitor brain electrical activity for the purpose of assessing anesthetic effect record electroencephalographic (EEG) activity from electrodes placed on the forehead. Systems can be subdivided into those that process spontaneous EEG and electromyographic (EMG) activity and those that acquire evoked responses to auditory stimuli (auditory evoked potential, AEP). After amplification and conversion of the analog EEG signal to the digital domain, various signal processing algorithms are applied to the frequency, amplitude, latency and/or phase relationship data derived from the raw EEG or AEP to generate a single number, often referred to as an “index” typically scaled between 100 and zero. This index represents the progression of clinical states of consciousness (‘awake’, ‘sedated’, ‘light anesthesia’, ‘deep anesthesia’), with a value of 100 being associated with the awake state, and values of zero occurring with an isoelectric EEG (or absent middle latency AEP). These processing algorithms may either be published and in the public domain or proprietary. Detailed descriptions of the various approaches to EEG signal processing, including bispectral analysis may be found elsewhere.<sup>57</sup> Artifact recognition algorithms intended to avoid contaminated, and therefore spurious, ‘index’ values are an important component of the software in most monitors.

Although EMG activity from scalp muscles can be considered an artifact from the viewpoint of pure EEG analysis, it may be an important source of clinically relevant information. Sudden appearance of frontal (forehead) EMG activity suggests somatic response to noxious stimulation resulting from inadequate analgesia and may give warning of impending arousal. For this reason, some monitors separately provide information on the level of EMG activity.

*1. Spontaneous EEG Activity Monitors.*

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**Bispectral Index.** Bispectral index (BIS) is a proprietary algorithm (Aspect Medical Systems) that converts a single channel of frontal EEG into an index of hypnotic level (bispectral index; BIS). BIS is available either as a separate device (BIS monitor; Aspect Medical Systems) or incorporated - under license from Aspect Medical Systems - in 'BIS modules' made by various anesthesia equipment manufacturers. To compute the BIS, several variables derived from the EEG time domain (burst-suppression analysis), frequency domain (power spectrum, bispectrum: interfrequency phase relationships) are combined into a single index of hypnotic level. BIS values are scaled from 0 to 100, with specific ranges (e.g., 40-60) reported to reflect a low probability of consciousness under general anesthesia. The weight factors for the various components in the multivariate model that generates the BIS were empirically derived from a prospectively collected database of over 1500 anesthetics. The BIS model accounts for the nonlinear stages of EEG activity by allowing different parameters to dominate the resulting BIS as the EEG changes its character with increasing plasma concentrations of various anesthetics, resulting in a linear decrease in BIS. As more data have become available and as methods and algorithms to suppress artifacts have been improved, revised iterations of the algorithm and optimized hardware have been released.

Several RCTs have compared outcomes with BIS-guided anesthetic administration versus standard clinical practice without BIS. In one RCT that enrolled 2500 patients at high risk of intraoperative awareness, explicit recall occurred in 0.17% of patients when BIS monitors were used and in 0.91% of patients managed by routine clinical practice ( $p < 0.02$ ).<sup>58</sup> A small ( $N = 30$ ) single-blinded RCT (i.e., the anesthesiologists were blinded to the recorded BIS values) compared BIS monitoring with clinical signs during cardiac surgery, and reported one episode of recall in the clinical signs group compared to no episodes in the BIS-monitored group ( $p > 0.50$ ).<sup>59</sup> In other RCTs, times to awakening, first response, or eye opening and consumption of anesthetic

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drugs were reduced with the use of BIS.<sup>8,60-68</sup>

One nonrandomized comparison of the use of BIS monitoring versus a cohort of historical controls (N = 12,771) found explicit recall occurring in 0.04% of the BIS monitored patients versus 0.18% of the historical controls ( $p < 0.038$ ).<sup>68</sup> Another prospective nonrandomized cohort study (N = 19,575) designed to establish the incidence of awareness with recall during routine general anesthesia and to determine BIS values associated with intraoperative awareness events reported no statistically significant difference when BIS was used (0.18% of patients) compared to when BIS was not used (0.10% of patients). Other nonrandomized comparative studies reported higher index values upon arrival in the PACU, shorter recovery times, and lower anesthetic usage among patients monitored with BIS compared to patients not monitored with BIS.<sup>70,71</sup> Numerous correlational studies reported Pk values for BIS ranging from 0.72 to 1.00 for awake versus loss of response following induction with propofol (with or without opioids); and from 0.79 to 0.97 for anesthetized versus first response.<sup>46-48,72-78</sup> One study reported a Pk value of 0.86 for movement from electrical stimulation.<sup>44</sup> Wide ranges of mean BIS values have been reported during various intraoperative times. Ranges of mean BIS values were as follows: before induction or baseline, 80 to 98; at or after induction, 37 to 70; during surgery, 20 to 58; at emergence or end of surgery, 42 to 96; and during postoperative recovery, 64 to 96.<sup>50,51,54-56,79-110</sup> Several case reports indicate that intraoperative events unrelated to titration of anesthetic agents can produce rapid changes in BIS values, e.g., cerebral ischemia or hypoperfusion, gas embolism, unrecognized hemorrhage, inadvertent blockage of anesthesia drug delivery.<sup>111-119</sup> Other case reports suggest that routine intraoperative events (e.g., administration of depolarizing muscle relaxants, activation of electromagnetic equipment or devices, patient warming or planned hypothermia) may interfere with BIS functioning.<sup>120-128</sup> Two case reports were found that reported patients experiencing intraoperative awareness in spite of monitored values indicating an

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adequate depth of anesthesia.<sup>129,130</sup> Finally, still other case reports suggested that certain patient conditions may affect BIS values.<sup>131-133</sup>

**Entropy.** Entropy (GE Healthcare Technologies) describes the irregularity, complexity, or unpredictability characteristics of a signal. A single sine wave represents a completely predictable signal (entropy = 0), whereas noise from a random number generator represents entropy = 1. The algorithm for calculation of entropy in the EEG signal (as incorporated in the Datex-Ohmeda S/5 entropy Module) is in the public domain and detailed descriptions have recently been published.<sup>134</sup>

Entropy is independent of absolute scales such as the amplitude or the frequency of the signal. The commercially available Datex-Ohmeda module calculates entropy over time windows of variable duration and reports two separate entropy values. State entropy (SE) is an index ranging from zero to 91 (awake), computed over the frequency range from 0.8 Hz to 32 Hz, reflecting the cortical state of the patient. Response Entropy (RE) is an index ranging from zero to 100 (awake) computed over a frequency range from 0.8 Hz to 47 Hz, containing the higher EMG-dominated frequencies, and will thus also respond to the increased EMG activity resulting from inadequate analgesia. No clinical trials or other comparative studies were found that examine the impact of entropy monitoring on the incidence of intraoperative awareness. One clinical trial reported reduced times to eye opening, response to command, and consumption of anesthetic drugs with the use of entropy monitoring.<sup>135</sup>

Correlational studies report the following Pk values for loss of consciousness: for RE, 0.83 to 0.97; for SE, 0.81 to 0.90.<sup>45,136-137</sup> For anesthetized versus first response, the following Pk values are reported: for RE, 0.85; and for SE, 0.82.<sup>46</sup> Ranges of mean RE and SE values were as follows: before induction or baseline, 98 (RE) and 89 to 91 (SE); during surgery, 34 to 52 (RE) and 50 to 63 (SE); and at emergence or end of surgery, 96 (RE) and 85 (SE).<sup>52,135,138,139</sup>

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**Narcotrend.** The Narcotrend (MonitorTechnik) is derived from a system developed for the visual classification of the EEG patterns associated with various stages of sleep. After artifact exclusion and Fourier transformation, the original electronic algorithm classified the raw (frontal) EEG according to the following system: A (awake), B (sedated), C (light anesthesia), D (general anesthesia), E (general anesthesia with deep hypnosis), F (general anesthesia with increasing burst suppression). The system included a series of sub-classifications resulting in a total of 14 possible sub-stages: A, B0–2, C0–2, D0–2, E0–1, and F0–1.<sup>140</sup> In the most recent iteration of the Narcotrend software (version 4.0), the alphabet-based scale has been “translated” into a dimensionless index, the Narcotrend index, scaled from zero (deeply anesthetized) to 100 (awake), with the stated intention of producing a scale quantitatively similar to the BIS index.

No clinical trials or other comparative studies were found that examine the impact of Narcotrend monitoring on the incidence of intraoperative awareness. One RCT has compared the use of Narcotrend-controlled versus clinically controlled anesthetic administration and found a shorter recovery time in the Narcotrend group (i.e., opened eyes) after termination of anesthesia.<sup>63</sup> Pk values for Narcotrend ranged from 0.93 to 0.99 for awake versus loss of response following induction with propofol combined with an opioid, and from 0.94 to 0.99 for anesthetized versus first response.<sup>47,48</sup> Reported mean Narcotrend values are as follows: after induction (loss of response), 72 to 80; and at emergence or end of surgery (spontaneously opened eyes), 80.<sup>73</sup>

**Patient State Analyzer.** The Patient State Index, or PSI (Physiometrix) is derived from a 4-channel EEG. The derivation of the PSI is based on the observation that there are reversible spatial changes in power distribution of quantitative EEG at loss and return of consciousness. The Patient State Index (PSI) has a range of 0 to 100, with decreasing values indicating decreasing levels of consciousness or increasing levels of sedation, similar to BIS, Entropy and Narcotrend. The PSI algorithm was constructed using stepwise, discriminant analysis based on



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multivariate combinations of quantitative EEG variables, derived after Fourier transformation of the raw EEG, and found to be sensitive to changes in the level of anesthesia.

No clinical trials or other comparative studies were found that examine the impact of PSI monitoring on the incidence of intraoperative awareness. One correlational study reported a Pk value of 0.70 for predicting response to command, with a sensitivity of 85.6% and specificity of 38.8%,<sup>77</sup> and another study reported a significant correlation of the PSI with unconsciousness.<sup>141</sup> Reported mean PSI values are as follows: before induction or baseline, 92; during surgery, 32; at emergence or end of surgery, 53; and during postoperative recovery, 81.<sup>141</sup>

**SNAP index.** The SNAPII (Everest Biomedical Instruments) calculates a “SNAP index” from a single channel of EEG. The index calculation is based on a spectral analysis of EEG activity in the 0-18 Hz and 80-420 Hz frequency ranges, and a burst suppression algorithm. There are no published data on the actual algorithm used to calculate the SNAP index, which is based on a composite of both low (0-40 Hz) and high (80-420 Hz) frequency components.

No clinical trials or other comparative studies were found that examine the impact of SNAP monitoring on the incidence of intraoperative awareness. One correlational study was found that reported a mean SNAP index of 71 to be predictive of a loss of consciousness in 95% of elective surgery patients.<sup>142</sup>

**Danmeter Cerebral State Monitor/Cerebral State Index.** The Danmeter CSM is a handheld device that analyzes a single channel EEG and presents a cerebral state ‘index’ scaled from 0-100. In addition, it also provides EEG suppression percentage and a measure of EMG activity (75-85 Hz).

No published literature was found that examined the impact of Danmeter CSM monitoring on the incidence of intraoperative awareness.

## *2. Evoked Brain Electrical Activity Monitors.*

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**AEP Monitor/2** (Danmeter). Auditory evoked potentials (AEP) are the electrical responses of the brainstem, the auditory radiation and the auditory cortex to auditory sound stimuli (clicks) delivered via headphones. The effects of anesthetics on AEP have been studied since the early 1980s.<sup>143-145</sup> The brainstem response is relatively insensitive to anesthetics while early cortical responses, known as the middle-latency AEP (MLAEP) change predictably with increasing concentrations of both volatile and intravenous anesthetics. The typical AEP response to increasing anesthetic concentrations is increased latency and decreased amplitude of the various waveform components. These signals are extremely small (less than one microvolt) necessitating extraction from the spontaneous EEG using signal averaging techniques. Prior to recent innovations, signal averaging was relatively time consuming (several minutes per averaged waveform). More recent signal filtering advances have resulted in an instrument (A-Line) that can record and rapidly update a single channel of AEP from forehead electrodes. From a mathematical analysis of the AEP waveform, the device generates an 'AEP-index' that provides a correlate of anesthetic concentration. The AEP index, or AAI, is scaled from 0 to 100. In contrast to many EEG indices, the AAI corresponding with low probability of consciousness is less than 25, rather than the higher numeric thresholds associated with the other monitors. The device is FDA approved but is not currently marketed in North America.

RCTs that compared MLAEP monitoring (e.g., to titrate anesthetics) to standard clinical practice without MLAEP reported reduced times to eye opening or orientation.<sup>63,64,146</sup> A Pk value of 0.79 was reported for loss of eyelash reflex following induction with propofol and an opioid,<sup>74</sup> and Pk values of 0.63 and 0.66 were reported for responsiveness following discontinuation of remifentanyl or sevoflurane, respectively.<sup>147</sup> One study reported a Pk value of 0.87 for movement,<sup>148</sup> and another study reported a Pk value of 0.99 for awareness after LMA insertion,<sup>149</sup> Descriptive studies reported ranges of mean values as follows: before induction or baseline, 73.5

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to 85; at or after induction, 33.4 to 61; during surgery, 21.1 to 37.8; at emergence or end of surgery, 24.6 to 40; and during postoperative recovery, 89.7.<sup>74,80,144,150-151</sup>

*C. Consultant and ASA Member Survey Findings.*

Consultants who participated in this Advisory typically either had a particular knowledge or an expressed interest in intraoperative awareness and brain function monitors. The majority of these consultants disclosed receipt of funds from or a financial interest in a company developing or manufacturing brain function monitors. Consultants were not asked to disclose similar relationships with other companies that may be indirectly affected by the use of brain function monitors. ASA members were randomly selected from a list of active members of the society.

The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to reduce the risk of *intraoperative awareness* for *all* patients. The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to reduce the risk of intraoperative awareness for *no* patient. The consultants agree that a brain electrical activity monitor should be used for patients with conditions that may place them at risk, patients requiring smaller doses of general anesthetics, trauma surgery, Cesarean section, and total intravenous anesthesia. They are equivocal regarding the use of brain electrical activity monitoring for cardiac surgery and emergency surgery. The ASA members agree with the use of such monitors for patients with conditions that may place them at risk, patients requiring smaller doses of general anesthetics, and patients undergoing cardiac surgery. They are equivocal regarding the use of these monitors for patients undergoing Cesarean section, emergency surgery, trauma surgery, and total intravenous anesthesia.

The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to assess intraoperative *depth of anesthesia* for *all* patients. The consultants and ASA members disagree with the statement that “a brain electrical activity monitor is valuable and

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should be used to assess intraoperative depth of anesthesia for *no* patient.” The consultants agree that a brain electrical activity monitor should be used to assess intraoperative depth of anesthesia for selected patients. The ASA members agree with the use of brain electrical activity monitors for patients with conditions that may place them at risk and patients requiring smaller doses of general anesthetics. They are equivocal regarding the use of such monitors for patients undergoing cardiac surgery, Cesarean section, emergency surgery, trauma surgery, and total intravenous anesthesia.

**Advisory.** Intraoperative monitoring of depth of anesthesia, for the purpose of minimizing the occurrence of awareness, should rely on multiple modalities, including clinical techniques (e.g., checking for clinical signs such as purposeful or reflex movement) and conventional monitoring systems (e.g., ECG, BP, HR, end-tidal anesthetic analyzer, capnography). The use of neuromuscular blocking drugs may mask purposeful or reflex movements, and adds additional importance to the use of monitoring methods that assure the adequate delivery of anesthesia.

Brain function monitors are dedicated to the assessment of the effects of anesthetics on the brain, and provide information that correlates with some depth of anesthesia indicators, such as plasma concentrations of certain anesthetics (e.g., propofol). In general, the indices generated by these monitors vary in parallel with other established correlates of depth of anesthesia, although the values generated by individual devices in any given anesthetic state differ among the various monitoring technologies. In addition, the values generated by individual devices in the face of a given depth of anesthesia achieved by different combinations of anesthetic drugs (e.g., with or without opioids) will also differ. In other words, a specific numerical value may not correlate with a specific depth of anesthesia. Furthermore, the measured values do not have uniform sensitivity across different anesthetic drugs or types of patients. As with other monitors, common occurrences in the OR may introduce artifacts into the values derived by these monitors (e.g., electrocautery, lasers, warming devices).

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The general clinical applicability of these monitors in the prevention of intraoperative awareness has not been established. While a single randomized clinical trial reported a decrease in the frequency of awareness in high-risk patients, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness in high-risk patients undergoing general anesthesia. In addition, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness for any other group of patients undergoing general anesthesia.

It is the consensus of the Task Force that brain function monitoring is not routinely indicated for patients undergoing general anesthesia, either to reduce the frequency of intraoperative awareness or to monitor depth of anesthesia. This consensus is based, in part, on the state of the literature and survey responses from the consultants and ASA membership, who generally disagree with the following statements: "Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness for all patients under general anesthesia," and "Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia for all patients under general anesthesia" (see above and tables 1 and 2).

It is the consensus of the Task Force that the decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients (e.g., light anesthesia). This consensus is based, in part, on the state of the literature and survey response patterns from consultants and ASA members regarding specific risk factors (see above and tables 1 and 2). The Task Force cautions that maintaining low brain function monitor values in an attempt to prevent intraoperative awareness may conflict with other important anesthesia goals (e.g., preservation of vital organ functions, minimizing the risks of aggravating existing co-morbidities<sup>152</sup>). It is the opinion of the Task Force that brain function monitors currently have the status of the many

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other monitoring modalities that are currently used in selected situations at the discretion of individual clinicians.

#### *IV. Intraoperative and Postoperative Interventions*

Intraoperative and postoperative interventions include: (1) the intraoperative administration of benzodiazepines to patients who may have become conscious, (2) providing a postoperative structured interview to patients to define the nature of the episode after an episode of intraoperative awareness has been reported, (3) providing a postoperative questionnaire to patients to define the nature of the episode, and (4) offering postoperative counseling or psychological support.

No studies were found that evaluated the efficacy of the intraoperative administration of benzodiazepines to patients who have unexpectedly become conscious in reducing the occurrence of awareness. Two randomized clinical trials examined retrograde amnesia by providing pictures as stimuli to awake patients before administration of midazolam and induction of general anesthesia. The studies reported no evidence of retrograde amnesia.<sup>41,42</sup> However, these studies did not examine the effect of administering a benzodiazepine to patients after the apparent occurrence of consciousness during general anesthesia.

Although several studies have applied structured interviews and questionnaires to obtain additional information about reported incidences of intraoperative awareness,<sup>4,11,26,28,153-157</sup> no studies were found that demonstrated improvements in patient well-being or psychological state following such interactions. No studies were found that followed up on the efficacy of counseling or psychological support provided to patients who experienced a documented incidence of intraoperative awareness.

The consultants are equivocal and ASA members agree that benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a patient has unexpectedly become conscious. The consultants strongly agree, and the ASA members agree that, once an episode of

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intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode. Both the consultants and ASA members are equivocal regarding whether a questionnaire should be given to define the nature of the episode. The consultants strongly agree, and the ASA members agree that, in documented cases of intraoperative awareness, patients should be offered counseling or psychological support. Finally, the consultants strongly agree, and the ASA members agree that, in documented cases of intraoperative awareness, an occurrence report concerning the event should be completed for the purpose of quality management.

**Advisory.** The Task Force consensus is that the decision to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious should be made on a case-by-case basis. . This consensus is based, in part, on the state of the literature and on responses from the Consultants and ASA members who generally agree with the following statement: “Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a patient has unexpectedly become conscious.” However, the Task Force believes that evidence from the literature is not sufficient to provide guidance regarding this issue. Finally, the Task Force cautions that the use of scopolamine may result in unintended side-effects (e.g., emergence delirium).

Practitioners should speak with patients who report recall of intraoperative events to obtain details of the event and to discuss possible reasons for its occurrence.<sup>††</sup> A questionnaire or structured interview may be used to obtain a detailed account of the patient’s experience. Once an episode of intraoperative awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management. Finally, the patient should be offered counseling or psychological support.

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<sup>††</sup> Refer to the ASA Director of Communications at 847-825-5586 for further information and guidance.

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## **Appendix 1: Summary of Practice Advisory**

### **Preoperative Evaluation**

- Review patient medical records for potential risk factors
  - Substance use or abuse
  - Previous episode of intraoperative awareness
  - History of difficult intubation or anticipated difficult intubation
  - Chronic pain patients on high doses of opioids
  - ASA status 4-5
  - Limited hemodynamic reserve
- Interview patient
  - Assess level of anxiety
  - Obtain information regarding previous experiences with anesthesia
- Determine other potential risk factors
  - Cardiac surgery
  - Cesarean section
  - Trauma surgery
  - Emergency surgery
  - Reduced anesthetic doses in the presence of paralysis
  - Planned use of muscle relaxants during the maintenance phase of general anesthesia
  - Planned use of nitrous oxide-opioid anesthesia
- Patients whom the individual clinician considers to be at substantially increased risk of intraoperative awareness should be informed of the possibility of intraoperative awareness when circumstances permit

### **Preinduction Phase of Anesthesia**

- Adhere to a checklist protocol for anesthesia machines and equipment to assure that the desired anesthetic drugs and doses will be delivered
- Verify the proper functioning of intravenous access, infusion pumps and their connections, including the presence of appropriate back-flow check valves
- The decision to administer a benzodiazepine prophylactically should be made on a case-by-case basis for selected patients (e.g., patients requiring smaller dosages of anesthetics)

### **Intraoperative Monitoring**

- Use multiple modalities to monitor depth of anesthesia
  - Clinical techniques (i.e., checking for purposeful or reflex movement)
    - Neuromuscular blocking drugs may mask purposeful or reflex movement
  - Conventional monitoring systems (e.g., ECG, BP, HR, end-tidal anesthetic analyzer, capnography)
  - Brain function monitoring
    - Not routinely indicated for general anesthesia patients
    - The decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients (e.g., light anesthesia)

### **Intraoperative and Postoperative Management**



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- The decision to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious should be made on a case-by-case basis
- Speak with patients who report recall of intraoperative events to obtain details of the event and to discuss possible reasons for its occurrence
- A questionnaire or structured interview may be used to obtain a detailed account of the patient's experience
- Once an episode of intraoperative awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management
- Offer counseling or psychological support to those patients who report an episode of intraoperative awareness

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## **Appendix 2: Literature Review and Consensus-Based Evidence**

For this Advisory, a literature review was used in combination with opinions obtained from experts and other sources (e.g., professional society members, open forums, web-based postings) to provide guidance to practitioners regarding intraoperative awareness. Both the literature review and opinion data were based on *evidence linkages*, consisting of directional statements about relationships between specific perioperative interventions and intraoperative awareness. The interventions for the evidence linkages are listed below:

### Preoperative Evaluation

- Focused history (i.e., medical records, patient interview, physical exam)
- Patient characteristics associated with risk of awareness
- Procedures associated with higher risk of intraoperative awareness
- Anesthetic techniques may be associated with higher risk of intraoperative awareness
- Informing patients of the possibility of intraoperative awareness

### Preinduction Phase of Anesthesia

- Check anesthesia delivery systems to reduce errors
- Prephylactic administration of benzodiazepines as co-anesthetics

### Intraoperative Monitoring

- Commonly used clinical techniques
- Conventional monitoring systems
- Brain function monitors
  - Spontaneous electrical activity (EEG/EMG)
    - Bispectral index (BIS)
    - Danmeter Cerebral State Monitor/Cerebral State Index
    - Entropy
    - Narcotrend
    - Patient state analyzer (PSA)
    - SNAP index
  - Evoked electrical activity (auditory evoked potential monitoring)
    - AEP Monitor/2

### Intraoperative and Postoperative Interventions

- Intraoperative use of benzodiazepines for unexpected consciousness
- Structured interview of patients who report recall of intraoperative events
- Questionnaire administered to patients who report recall of intraoperative events
- Patient counseling for patients who report recall of intraoperative events

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*A. State of the Literature.*

A study or report that appears in the published literature is included in the development of an advisory if the study: (1) is related to one of the specified linkage statements, (2) reports a finding or set of findings that can be tallied or measured (e.g., articles that contain only opinion are not included), and (3) is the product of an original investigation or report (i.e., review articles or follow-up studies that summarize previous findings are not included).

For the literature review, potentially relevant studies were identified via electronic and manual searches of the literature. The electronic search covered a 40-year period from 1966 through 2005. The manual search covered a 36-year period of time from 1970 through 2005. Over 1500 citations were initially identified, yielding a total of 711 non-overlapping articles that addressed topics related to the evidence linkages and met our criteria for inclusion. Following review of the articles, 389 studies did not provide direct evidence, and were subsequently eliminated. A total of 322 articles contained direct linkage-related evidence. No evidence linkage contained enough studies with well-defined experimental designs and statistical information to conduct a quantitative analysis (i.e., meta-analysis).

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa ( $\kappa$ ) statistic for two-rater agreement pairs were as follows: (1) type of study design,  $\kappa = 0.60$  to  $0.85$ ; (2) type of analysis,  $\kappa = 0.60$  to  $0.93$ ; (3) evidence linkage assignment,  $\kappa = 0.77$  to  $0.88$ ; and (4) literature inclusion for database,  $\kappa = 0.76$  to  $1.00$ . Three-rater chance-corrected agreement values were: (1) study design,  $Sav = 0.82$ ,  $Var(Sav) = 0.007$ ; (2) type of analysis,  $Sav = 0.73$ ,  $Var(Sav) = 0.008$ ; (3) linkage assignment,  $Sav = 0.69$ ,  $Var(Sav) = 0.012$ ; (4) literature database inclusion,  $Sav = 0.84$ ,  $Var(Sav) = 0.014$ . These values represent moderate-to-high levels of agreement.

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The primary focus of this Advisory was to examine studies with hypothesis-driven research designs, such as RCTs, that examined the effect of an intervention (such as a brain function monitor) on reducing the occurrence or frequency of intraoperative awareness. To date, only two randomized controlled trials were found that reported intraoperative awareness as the primary study endpoint.<sup>55,56</sup> Additional controlled trials will be necessary before data from published literature can be aggregated to provide a basis for quantitative evidence (i.e., meta-analysis).

Several other RCTs were reviewed that reported primary outcomes other than intraoperative awareness, including emergence time, consumption of anesthetic drugs and recovery characteristics. In addition, many other published studies applied non-hypothesis driven research designs to obtain non-causal or indirect data. For example, descriptive literature (i.e., reports of frequency or incidence) may provide an indication of the scope of the problem. Correlational or predictive data provides information regarding the direction and strength of association of values obtained from patient monitoring devices with other intraoperative measures such as blood concentrations of anesthetic drugs, time to loss of eyelash reflex, and time to awakening. Case reports are typically employed as a forum for reporting and recognizing unusual or unintended benefits or harms. Often, case reports, as well as descriptive or correlational data provide useful hypotheses-generating information that may stimulate additional causal examination of the topic of intraoperative awareness.

Future studies should focus on prospective methodologies, when possible, that utilize traditional hypothesis testing techniques. Use of the following methodological procedures for assessing the impact of interventions for intraoperative awareness is recommended: (1) comparison studies assessing the efficacy of one technique versus other techniques; (2) random assignment to treatment groups with blinding if appropriate; and (3) full reporting of sample size, effect size estimates, test scores, measures of variability, and p-values. The Task Force recognizes that conducting such

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studies may be difficult and expensive, because intraoperative awareness is a very low incidence event. The required sample size for a RCT to test the impact of an intervention (e.g., brain function monitor) on the incidence of intraoperative awareness is invariably large. The Task Force also recognizes that, with low incidence data, a difference in the recording of one or two cases of intraoperative awareness can affect the statistical significance of study findings.

Limiting the study to patient subgroups thought to have a higher risk for intraoperative awareness (e.g., cardiac surgery, cesarean section, emergency trauma surgery) may allow for a smaller sample size and provide useful information regarding these subgroups. However, the Task Force recognizes that the generalizability of these findings to the larger population of general anesthesia patients may be limited.

#### *B. Consensus-Based Evidence.*

Consensus was obtained from multiple sources, including: (1) survey opinion from Consultants who were selected based on their knowledge or expertise in intraoperative awareness, (2) survey opinions from a randomly selected sample of active members of the American Society of Anesthesiologists, (3) testimony from attendees of three open forums held at national anesthesia meetings,<sup>§§</sup> (4) internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 60% (N = 57/95) for Consultants, and 30% (N=151/500) for the ASA membership. Survey results are presented in the text of the document and in tables 1 and 2.

Ninety-one percent of the consultants and 72% of the ASA members indicated that they had personally used a brain function device in the past. Fifty-seven percent of the consultants indicated that they make use in their current practice of a brain function device either always (11.1%), frequently (20.4%), or sometimes (25.9%). Thirty-six percent of the ASA members

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<sup>§§</sup> American Society of Anesthesiologists, Annual Meeting, October 25, 2004 in Las Vegas, NV; International Anesthesia Research Society, 79<sup>th</sup> Clinical and Scientific Congress, March 12, 2005 in Honolulu, HI; and Association of University Anesthesiologists 52<sup>nd</sup> Annual Meeting, May 6, 2005 in Baltimore, MD.

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indicated that they make use in their current practice of a brain function device either always (6.0%), frequently (13.4%), or sometimes (16.8%).

The Consultants were also asked to indicate which, if any, of the evidence linkages would change their clinical practices if the Advisory was instituted (table 3). The rate of return was 18% (N = 17/95). The percent of responding Consultants expecting *no change* associated with each linkage were as follows: preoperative evaluation - 82%; informing patients of the possibility of intraoperative awareness - 65%; check anesthesia delivery systems - 94%; prophylactic use of benzodiazepines as co-anesthetics - 100%; use of clinical techniques to monitor for intraoperative awareness - 94%; use of conventional monitoring systems to monitor for intraoperative awareness - 100%; use of brain function monitors to monitor for intraoperative awareness - 59%; intraoperative use of benzodiazepines for unexpected consciousness - 100%; use of a structured interview for patients who report recall of intraoperative events - 41%; use of a questionnaire for patients who report recall of intraoperative events - 53% and counseling for patients who report recall of intraoperative events - 76%. Seventy-one percent of the respondents indicated that the Advisory would have *no effect* on the amount of time spent on a typical case. Four respondents (24%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of this Advisory. The amount of increased time anticipated by these respondents ranged from 1 to 20 minutes.

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Table 1. Consultant Survey Responses \*\*\*

		Percent Responding to Each Item					
		Strongly				Strongly	
	N	Agree	Agree	Uncertain	Disagree	Disagree	
<b>Preoperative evaluation:</b>							
1. Helpful to identify pts at risk of intraoperative awareness	57	31.6	43.9*	7.0	10.5	7.0	
2. A preop eval should include:							
Review of medical records	48	41.7	45.8*	4.2	6.3	2.1	
A physical examination	47	21.3	34.0*	17.0	25.5	2.1	
A patient/family interview	48	39.6	35.4*	14.6	8.3	2.1	
3. Potential patient risk factors:							
Substance use or abuse	54	38.9	42.6*	5.6	13.0	0.0	
Pt history of intraop awareness	55	52.7*	29.1	10.9	7.3	0.0	
Limited hemodynamic reserve	54	38.9	40.7*	13.0	7.4	0.0	
ASA status of 4 or 5	54	24.1	48.1*	20.4	7.1	0.0	
4. Procedures/ anesthetic techniques that may place a patient at risk for intraop awareness:							
Cesarean section under GA, cardiac surgery, trauma, emergency surgery	57	75.4*	24.6	0.0	0.0	0.0	
Planned use of reduced doses of anesthetics in the presence of paralysis	56	66.1*	25.0	5.4	1.8	1.8	
Planned use of muscle relaxants for maintenance	57	26.4	45.6*	8.8	17.5	1.8	
Planned use of total intravenous anesthesia	57	10.5	33.3	24.6*	21.1	10.5	
Planned use of volatile anesthetics	57	3.5	5.3	12.3	57.9*	21.1	
Planned use of nitrous oxide-narcotic anesthesia	57	29.8	35.1*	14.0	19.3	1.8	
Preoperative or intraoperative use of beta-blockers under general anesthesia	57	5.3	35.1	26.3*	29.8	3.5	
Rapid-sequence induction	57	5.3	29.8	19.3*	42.1	3.5	
5. All pts should be informed of the possibility of intraop awareness	57	10.5	31.6	5.3	42.1*	10.5	
6. Only patients considered to be at elevated risk of intraop awareness should be informed of the possibility of intraop awareness	40	17.5	60.0*	5.0	7.5	10.0	

\*\*\* N = the number of consultants who responded to each item. An astrisk beside a percentage score indicates the median.

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	<u>N</u>	<u>Strongly Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly Disagree</u>
7. Informing the pt preoperatively of the risk of intraop awareness increases the actual risk of intraoperative awareness	53	3.8	5.7	30.2	35.8*	24.5

**Preinduction activities:**

8. The functioning of anesthesia delivery systems should be checked preoperatively to reduce the risk of intraop awareness	57	77.2*	17.5	1.8	3.5	0.0
9. A benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraop awareness:						
<u>For all patients</u> under GA	54	7.4	24.1	1.9	33.3*	33.3
<u>For no patients</u> under GA	54	3.7	3.7	3.7	46.3*	42.6
For pts with conditions that may place them at risk for intraop awareness	53	20.8	58.5*	7.5	7.5	5.7
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	53	17.0	43.4*	11.3	20.8	7.5
For patients undergoing cardiac surgery	54	22.2	44.4*	11.1	16.7	5.6
For patients undergoing Cesarean section under GA	54	7.4	29.6	20.4*	31.5	11.1
For patients undergoing emergency surgery under GA	53	15.1	30.2	20.8*	28.3	5.7
For patients undergoing trauma surgery under GA	54	16.7	35.2*	20.4	22.2	5.6
For patients undergoing total intravenous anesthesia	54	16.7	31.5	18.5*	24.1	9.3

**Intraoperative Monitoring:**

10. Commonly used clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to detect intraop consciousness	53	18.9	47.2*	5.7	18.9	9.4
11. Conventional monitoring systems are valuable and should be used to detect intraoperative consciousness	53	22.6	41.5*	5.7	24.5	5.7



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	<u>N</u>	<u>Strongly</u> <u>Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly</u> <u>Disagree</u>
12. Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness:						
<u>For all patients</u> under GA	57	7.0	21.1	19.3	15.8*	36.8
<u>For no patients</u> under GA	56	3.6	7.1	14.3	35.7*	39.3
For pts with conditions that may place them at risk for intraop awareness	57	36.8	26.3*	14.0	14.0	8.8
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	56	26.8	32.1*	14.3	19.6	7.1
For patients undergoing cardiac surgery	57	28.1	21.1	26.3*	14.0	10.5
For patients undergoing Cesarean section under GA	57	31.6	21.1*	21.1	17.5	8.8
For patients undergoing emergency surgery under GA	57	21.1	28.1	24.6*	17.5	8.8
For patients undergoing trauma surgery under GA	57	26.3	24.6*	24.6	15.8	8.8
For patients undergoing total intravenous anesthesia	56	16.1	39.3*	23.2	14.3	7.1
13. Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia:						
<u>For all patients</u> under GA	56	12.5	21.4	10.7	14.3*	41.1
<u>For no patients</u> under GA	54	9.3	5.6	9.3	37.0*	38.9
For pts with conditions that may place them at risk for intraop awareness	56	33.9	30.4*	8.9	14.3	12.5
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	56	28.6	35.7*	10.7	10.7	14.3
For patients undergoing cardiac surgery	56	26.8	28.6*	16.1	14.3	14.3
For patients undergoing Cesarean section under GA	56	28.6	32.1*	12.5	12.5	14.3

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	<u>N</u>	<u>Strongly Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly Disagree</u>
For patients undergoing emergency surgery under GA	57	21.1	36.8*	10.5	17.5	14.0
For patients undergoing trauma surgery under GA	57	22.8	38.6*	10.5	14.0	14.0
For patients undergoing total intravenous anesthesia	57	26.3	35.1*	17.5	8.8	12.3

#### **Intraoperative & Postoperative Interventions:**

14. Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a pt has unexpectedly become conscious	57	21.1	26.3	15.8*	21.1	15.8
15. Once an episode of intraoperative awareness has been reported, a <u>structured interview</u> should be conducted to define the nature of the episode	57	63.2*	31.5	1.8	0.0	0.0
16. Once an episode of intraop awareness has been reported, a <u>questionnaire</u> should be given to define the nature of the episode	57	10.5	19.3	36.8*	28.1	5.3
17. Once an episode of intraop awareness has been reported and documented, the pt should be offered counseling or psychological support	56	69.6*	25.0	5.4	0.0	0.0
18. Once an episode of intraop awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management	57	54.4*	40.4	0.0	5.3	0.0

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Table 2. ASA Member Survey Responses<sup>†††</sup>

<b>Preoperative evaluation:</b>	<u>N</u>	<u>Percent Responding to Each Item</u>				
		<u>Strongly Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly Disagree</u>
1. Helpful to identify pts at risk of intraoperative awareness	146	27.4	46.6*	14.4	10.3	1.4
2. A preop eval should include:						
Review of medical records	121	38.8	47.9*	7.4	5.0	0.8
A physical examination	118	23.7	37.3*	18.6	17.8	2.5
A patient/family interview	121	46.3	43.0*	6.6	3.3	0.8
3. Potential patient risk factors:						
Substance use or abuse	147	31.3	44.2*	16.3	6.8	1.4
Pt history of intraop awareness	146	45.2	31.5*	11.0	11.6	0.7
Limited hemodynamic reserve	145	46.3	38.6*	6.9	6.9	1.4
ASA status of 4 or 5	145	33.1	40.7*	11.0	13.1	2.1
4. Procedures/ anesthetic techniques that may place a patient at risk for intraop awareness:						
Cesarean section under GA, cardiac surgery, trauma, emergency surgery	151	70.2*	27.2	0.7	1.3	0.7
Planned use of reduced doses of anesthetics in the presence of paralysis	148	48.6	44.6*	4.1	2.7	0.0
Planned use of muscle relaxants for maintenance	147	21.1	34.7*	16.3	26.5	1.4
Planned use of total intravenous anesthesia	146	13.0	26.7	24.0*	32.2	4.1
Planned use of volatile anesthetics	148	0.7	10.1	10.1	63.5*	15.5
Planned use of nitrous oxide-narcotic anesthesia	147	11.6	46.9*	18.4	19.7	3.4
Preoperative or intraoperative use of beta-blockers under general anesthesia	148	4.7	31.1	23.0*	36.5	4.7
Rapid-sequence induction	148	3.4	31.1	18.9*	41.9	4.7
5. All pts should be informed of the possibility of intraop awareness	147	15.0	28.6	10.9*	40.1	5.4
6. Only patients considered to be at elevated risk of intraop awareness should be informed of the possibility of intraop awareness	112	17.0	49.1*	7.1	21.4	5.4

<sup>†††</sup> N = the number of members who responded to each item. An astrisk beside a percentage score indicates the median.

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	<u>N</u>	<u>Strongly</u> <u>Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly</u> <u>Disagree</u>
7. Informing the pt preoperatively of the risk of intraop awareness increases the <i>actual</i> risk of intraoperative awareness	147	2.7	10.9	33.3	38.8*	14.3

**Preinduction activities:**

8. The functioning of anesthesia delivery systems should be checked preoperatively to reduce the risk of intraop awareness	148	60.8*	37.8	0.7	0.7	0.0
9. A benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraop awareness:						
<u>For all patients</u> under GA	150	15.3	34.0	6.0*	30.7	14.0
<u>For no patients</u> under GA	144	0.7	2.8	3.5	50.7*	42.4
For pts with conditions that may place them at risk for intraop awareness	148	37.8	56.1*	3.4	2.7	0.0
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	150	31.3	60.7*	4.7	3.3	0.0
For patients undergoing cardiac surgery	147	39.5	48.3*	9.5	2.7	0.0
For patients undergoing Cesarean section under GA	151	13.2	23.2	27.8*	28.5	7.3
For patients undergoing emergency surgery under GA	151	21.1	42.4*	21.9	13.9	0.7
For patients undergoing trauma surgery under GA	150	24.0	44.7*	22.7	8.7	0.0
For patients undergoing total intravenous anesthesia	150	23.3	48.0*	14.0	12.7	2.0

**Intraoperative Monitoring:**

10. Commonly used clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to detect intraop consciousness	151	10.6	50.3*	21.2	13.9	4.0
11. Conventional monitoring systems are valuable and should be used to detect intraoperative consciousness	150	20.7	56.7*	9.3	10.7	2.7

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	<u>N</u>	<u>Strongly</u> <u>Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly</u> <u>Disagree</u>
12. Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness:						
<u>For all patients</u> under GA	149	10.7	10.7	16.1	37.6*	24.8
<u>For no patients</u> under GA	146	2.7	3.4	24.7	44.5*	24.7
For pts with conditions that may place them at risk for intraop awareness	147	21.1	48.3*	19.0	10.2	1.4
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	147	19.7	38.8*	24.5	13.6	3.4
For patients undergoing cardiac surgery	148	20.3	33.8*	30.4	12.2	3.4
For patients undergoing Cesarean section under GA	148	12.8	34.5	25.0*	23.0	4.7
For patients undergoing emergency surgery under GA	146	17.8	26.0	28.8*	24.0	3.4
For patients undergoing trauma surgery under GA	148	18.9	29.7	28.4*	19.6	3.4
For patients undergoing total intravenous anesthesia	148	13.5	35.1	25.7*	20.3	5.4
13. Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia:						
<u>For all patients</u> under GA	150	12.0	9.3	16.0	30.7*	32.0
<u>For no patients</u> under GA	147	2.7	4.8	24.5	41.5*	26.5
For pts with conditions that may place them at risk for intraop awareness	148	20.3	43.2*	20.9	10.8	4.7
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	149	20.1	37.6*	20.8	15.4	6.0
For patients undergoing cardiac surgery	149	20.1	27.5	28.2*	19.5	4.7
For patients undergoing Cesarean section under GA	149	13.4	30.2	22.8*	26.2	7.4
For patients undergoing emergency surgery under GA	149	14.8	26.8	24.8*	26.8	5.4
For patients undergoing trauma surgery under GA	149	16.1	28.9	25.5*	24.2	5.4
For patients undergoing total intravenous anesthesia	149	15.4	32.9	24.8*	20.1	6.7

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	<u>N</u>	<u>Strongly Agree</u>	<u>Agree</u>	<u>Uncertain</u>	<u>Disagree</u>	<u>Strongly Disagree</u>
<b>Intraoperative &amp; Postoperative Interventions:</b>						
14. Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a pt has unexpectedly become conscious	151	33.1	49.7*	9.9	7.3	0.0
15. Once an episode of intraoperative awareness has been reported, a <u>structured interview</u> should be conducted to define the nature of the episode	151	49.0	43.0*	7.3	0.7	0.0
16. Once an episode of intraop awareness has been reported, a <u>questionnaire</u> should be given to define the nature of the episode	151	19.9	21.9	38.4*	18.5	1.3
17. Once an episode of intraop awareness has been reported and documented, the pt should be offered counseling or psychological support	151	44.4	39.1*	14.6	1.3	0.7
18. Once an episode of intraop awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management	151	47.7	41.1*	9.3	1.3	0.7

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<sup>†††</sup> The references listed here do not represent a complete bibliography of the literature reviewed. A complete bibliography is available by writing to the American Society of Anesthesiologists or by accessing the *Anesthesiology* Web site: <http://www.anesthesiology.org>

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## THE EXECUTION OF STANLEY TOOKIE WILLIAMS

**Eyewitness: Prisoner did not die meekly, quietly**

- Kevin Fagan, Chronicle Staff Writer

Wednesday, December 14, 2005



It took 36 agonizing minutes to get to the defining moment of Stanley Toookie Williams' execution by lethal injection early Tuesday, and when it came it shot through the stuffy, crowded witness room like lightning.

Williams lay dead, strapped to his gurney. It was 12:35 a.m. The prison guards had just ordered the 39 witnesses to leave, and the first to go were three friends Williams had asked to watch his final moments. It was so quiet that when one man jangled his pocket change, it echoed off the walls.

Then, just as they crossed the doorway to the chilly outdoors, the three whipped their heads back and screamed in unison: "The state of California just killed an innocent man!" Across the room sat Lora Owens, stepmother of one of the murder victims -- and the stone face she'd worn for the entire execution dissolved. Her eyes filled with horror, and she burst into tears, pressing a tissue to her face.

And there it was: The twin emotions enveloping the execution of the 12th man put to death by California since capital punishment was revived in 1992 after a quarter-century hiatus.

On one side were the furious supporters of Williams, 51, who co-founded the Crips gang in the early 1970s but later renounced violence while in prison and wrote influential books advocating peace. On the other was the trail of survivors left grieving for the four people he was convicted of shotgunning to death in 1979 in Southern California.

The two sides never came to a meeting of the minds. Not even in the end.

The dramatics seemed far from anybody's mind when the execution began precisely at 11:59 p.m. Monday.

The oval door of the death chamber popped open -- it looks like a submarine hatch -- and Williams shuffled in with a green-uniformed guard on each side, loosely holding his arms, and three following behind. His wrists were handcuffed to a waist chain. His eyes were calm behind steel-frame glasses, lips set firmly above a gray beard.

**E.R. 0170**



It looked like it would be just like the nine lethal injections before it: controlled, noiseless, practically antiseptic.

With a chest like a barrel and bulging arms the size of toned thighs, Williams had to squeeze with his guards along the 7 1/2-foot-wide chamber's glass window just to get to the side of the gurney. There, he lay down slowly, and after the guards unlocked his wrists, he helpfully spread his arms along the gurney and became still. In two minutes, the team had him lashed down tight: black straps with buckles at his shoulders, chest, waist, knees and feet, and brown-leather Velcro straps at his wrists.

Williams stared straight up and his lips moved rapidly, praying quietly. At one point, a tiny tear slid down his cheek.

The three guards left, and five others walked in.

It was time to insert the needles.

Watching tensely the whole while were the 39 witnesses. They'd been marched into the witness room by a phalanx of guards a few minutes before midnight and placed in a half-circle around the death chamber -- 11 in chairs at the window, the rest on risers against three walls. It's impossible to tell who many witnesses are, because by prison rules nobody can move from their spot or talk, but they always consist of four groups: Supporters of the condemned man, supporters of his victims, 17 media representatives, and more than dozen law enforcement and legal officials.

In this execution, at least five were related to the four people Williams was convicted of killing -- convenience store clerk Albert Owens, 26, and motel owners Yen-I Yang, 76, Tsai-Shai Chen Yang, 63, and their daughter Yee-Chen Lin, 43. Prison sources said the victim witnesses were all from the Owens family.

The three who shouted on their way out were led by bushy-haired Barbara Becnel, co-author of his anti-gang books. Also witnessing on Williams' behalf were his attorney, Peter Fleming, and another lawyer.

Nobody said a word at first. Everybody stood rigidly.

The first catheter slid in messily at the crook of Williams' right elbow, taking just two minutes to seat but spurting so much blood at the needle point that a cotton swab was soaked, shining deep red before it was taped off.

Then came the real trouble. A medical technician, a woman with short black hair, had to poke for 11 minutes before her needle hit home.

At the first stick, at 12:04, Williams clenched his toes. At 12:05, he struggled mightily against the straps holding him down to look up at the press gallery behind him, dishing out a hard stare for six long seconds. By 12:10 a.m., the medical tech's lips were tight and white and sweat was pooling on her forehead as she probed Williams' arm.

"You guys doing that right?" Williams asked angrily, frustration clear on his face. The female guard whispered something back; it was hard to hear anything through the thick

E.R. 0171

glass walls of the death chamber. One guard, jaw clenched tightly, patted Williams' shoulder as if to comfort him.

Outside the chamber, Becnel stood with her two companions -- a woman and a man -- at the only window with a clear line of sight into Williams' eyes, and it was as if they were trying to will themselves right through the glass to stand alongside their friend. They thrust their fists up in what seemed to be a black power salute, and the man called out softly, "Tookie." They whispered "I love you" and "God bless you" as they looked adoringly into Williams' eyes.

Meanwhile, 10 feet away, Lora Owens sat stiffly, looking through the glass at the top of Williams' head. Her thick red hair never moved, and her mouth was a tight line. A blond woman sitting next to her put her arm around her, and then removed it and clasped her hands in her lap.

At 12:16 a.m., the second needle was inserted. His hands were taped, mummy-like, to the gurney arms. The guards hurried out the door and sealed it, leaving Williams alone with two clear intravenous lines snaking off his arms and into holes in the back wall of the death chamber.

At 12:18 a.m., a female prison guard loudly read off the warrant proclaiming that prisoner number C29300 had been sentenced to die and "the execution shall now proceed." Williams forced his head up one last time to stare into the eyes of his five friends -- and he kept it raised until he passed out 1 1/2 minutes later from the first salvo of chemicals, sodium pentothal to put him to sleep. Sorrow washed over the faces of Becnel and her female companion as his head sank, and they clasped their hands in prayer.

From there on it was a nail-biting vigil for everyone outside staring in. There was no way to know which chemicals were being administered because the plungers sending them into the intravenous tubes are pressed by unseen hands behind the chamber walls. Williams' chest heaved several times as he lay with his eyes closed, but somewhere in the 15 minutes from 12:20 to 12:35 a.m., the executioners filled his veins with pancuronium bromide to stop his breathing, then potassium chloride to stop his heart.

Finally, someone behind the walls called out, "He's flatlined," and it was over. A hand shoved a paper through a peephole in the witness room, a guard read off a quick statement affirming Williams' death, and 30 seconds later the room was cleared.

That's when the outburst happened. It was the first time since California restarted executions in 1992 that anybody had yelled or even spoken loudly during the grim procedure -- and as much as anything, that is what set this execution apart.

All of the other men killed by lethal injection lay so quietly on the gurney that, except for a few small movements, it was hard to tell if they were even awake. Even in the two gassings at San Quentin that preceded the injections, Robert Alton Harris and David Edwin Mason faced their ends stoically. The witnesses, too, have never done more than mouth a few silent words and cry quietly -- and the victim and prisoner advocates certainly never reacted to each other.

Williams and his friends were different.

E.R. 0172

It was like they were determined to get through his final minutes on Earth on their own terms -- even up to the tradition of the condemned man issuing a final statement. Williams, ever-defiant against the system he considered unfair, gave no final words to Warden Steve Ornoski, who said later that Williams chose instead to leave his final message with Becnel. Sources said she may reveal it at a funeral in Los Angeles on Tuesday.

The main complication in the death chamber this time was the excruciatingly long wait for the poisons to work. During the last execution, when triple-killer Donald Beardslee was killed in January, the actual injection process took four fewer minutes; injections for "Freeway Killer" William Bonin required only four minutes in 1996. But prison officials had an explanation.

He was a big man," Warden Steve Ornoski said in a post-execution briefing. The techs didn't have to administer extra shots of chemicals, he said; the poisons just needed time to work.

It made sense. Williams was the most muscular man put to death in the modern era of executions in California, and it appeared as if his bulky body was fighting off the inevitable, even after consciousness and the ability to move had fled.

This was not a man who went meekly.

---

*This was the sixth execution witnessed by Kevin Fagan. E-mail him at [kfagan@sfgchronicle.com](mailto:kfagan@sfgchronicle.com).*

A look at California's 647 Death Row inmates

Here is a statistical summary of inmates sentenced to death in California.

By ethnicity

White	39.51%
Black	35.34%
Hispanic	18.98%
Other	6.17%

By age range

10-19	0%
20-29	4.8%
30-39	31.4%
40-49	36.5%
50-59	21.3%
60-69	5.3%
70-79	0.8%
80-89	0%
90 and above	0%

Figures as of December 2005. Numbers may not total 100% because of rounding

Executions Name, year executed and time spent on Death Row:

Robert Alton Harris (1992; 13 years, 1 month)

**E.R. 0173**

Keith Daniel Williams (1996; 17 years)  
Robert Lee Massie (2001; 21 years, 10 months)  
Darrell Keith Rich (2000; 19 years, 1 month)  
Kelvin Malone\* (1999; 15 years, 6 months)  
Stephen Wayne Anderson (2002; 20 years, 6 months)  
Donald Beardslee (2005; 20 years, 10 months)  
Stanley Tookie Williams (2005; 24 years, 8 months)  
William George Bonin (1996; 13 years, 1 month)  
Manuel Babbitt (1999; 16 years, 10 months)  
Jaturun Siripongs (1999; 15 years, 9 months)  
David Edwin Mason (1993; 9 years, 7 months)  
Thomas M. Thompson (1998; 14 years, 1 month)  
\* Extradited to Missouri and executed in that state.

By sentencing county

County	Total	Percentage
Alameda	86	13.3%
Santa Clara	52	8.0
Contra Costa	34	5.3
San Mateo	28	4.3
Sonoma	8	1.2
Napa	4	0.6
Solano	4	0.6
Marin	2	0.3
San Francisco	2	0.3

Sources: California Department of Corrections, Associated Press

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FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MICHAEL ANGELO MORALES,

Plaintiff,

v.

RODERICK HICKMAN, Secretary; STEVEN  
ORNOSKI. Warden,

Defendants.

CAPITAL CASE

C 06-219 JF

DECLARATION OF DR. JACK ST. CLAIR

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FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

**MICHAEL ANGELO MORALES,**

Plaintiff,

v.

**RODERICK HICKMAN, Secretary; STEVEN  
ORNOSKI, Warden,**

Defendants.

**CAPITAL CASE**

**C 06-219 JF**

**DECLARATION OF DR. JACK  
ST. CLAIR**

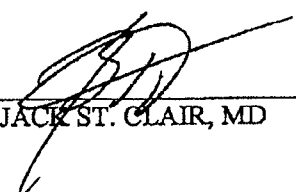
I, Jack St. Clair, MD, declare:

1. I am physician licensed to practice in the state of California since 2000.
2. I am currently the Chief Medical Officer at the California State Prison at San Quentin, a position I have held since September 1, 2005.
3. I have been asked to respond to the Court's inquiry about "the nature and significance of any difficulties arising in the administration of the lethal-injection protocol in connection with the recent executions of Donald J. Beardslee, Stanley Tookie Williams, and Clarence Ray Allen."

- 1 4. I personally attended the executions of Williams on December 13, 2005, and of Allen  
2 on January 17, 2006. I have also reviewed the execution log from both of those cases.  
3 I did not attend the execution of Beardslee on January 19, 2005, but have reviewed the  
4 execution log for that case. A true and correct copy of the execution log for each of  
5 the cases is attached to this declaration.
- 6 5. The Beardslee log indicates there was some difficulty inserting the left arm IV line.  
7 Once that was completed there were no problems with delivery of the drugs or  
8 completion of the execution.
- 9 6. During the Williams execution there was some difficulty inserting the left arm IV line.  
10 Once that was completed there were no problems with delivery of the drugs or  
11 completion of the execution.
- 12 7. There were no difficulties or complications during the Allen execution. After the  
13 initial dose of potassium chloride was injected an agonal rhythm continued on the  
14 heart monitor. A second dose of potassium chloride was injected, resulting in a flat  
15 line and pronouncement of death.

16 I declare under penalty of perjury under the laws of the United States that the  
17 foregoing is true and correct.

18 Executed January 20, 2006.

19  
20  
21   
22 JACK ST. CLAIR, MD  
23  
24  
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27  
28

## LETHAL INJECTION - EXECUTION RECORD

No. C-82702 Name Beardslee Age \_\_\_\_\_  
Date Received \_\_\_\_\_ Date Executed \_\_\_\_\_  
Doctors \_\_\_\_\_

OPERATION	TIME	RATE		REMARKS
		HEART	RESP.	
Injection Drugs on Hand	1200		16	
Prisoner Entered Chamber	1255		24	
Saline Solution IV Set and Running	1202		20	@ 5 difficulty 1214 (6) C 6
Chamber Door Locked	1217			
Drug - Sodium Pentothal Started	1218		20	
Drug - Pancuronium Bromide Started	1222			
Drug - Potassium Chloride Started	1225			injection completed 1222
Special Comments				
last line EKG	1229			
Respirations Ceased				
Cardiac Monitor - Flatline				
Prisoner Pronounced Dead				

Disposition of Remains:



## LETHAL INJECTION - EXECUTION RECORD

No. C 29300 Name Stanley T. Williams Age 51  
Date Received \_\_\_\_\_ Date Executed 12/13/05  
Doctors DR Wilson DR St Clair

OPERATION	TIME	RATE		REMARKS
		HEART	RESP.	
Injection Drugs on Hand	2403			2405 RT IV 2408 LT IV 2417
Prisoner Entered Chamber	2359		28	Calm & Cooperative
Saline Solution IV Set and Running	2406/2408			
Chamber Door Locked		83	20	
Drug - Sodium Pentothal Started	2422	90	24	Resp S2A/low 2425
Drug - Pancuronium Bromide Started	2428	115	0	Saline 2427
Drug - Potassium Chloride Started	2432	70	0	Saline 2432
Special Comments				
Death 2435				LT IV failed Restarted
Respirations Ceased				
Cardiac Monitor - Flatline				
Prisoner Pronounced Dead				
Disposition of Remains:				

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

CALIFORNIA STATE PRISON  
SAN QUENTIN, CALIFORNIA

## LETHAL INJECTION - EXECUTION RECORD

No. \_\_\_\_\_ Name CLARENCE ROY ALLAN Age 76  
 Date Received 1-16-06 Date Executed 1-17-06  
 Doctors ST. CLAIR

OPERATION	TIME	RATE		REMARKS
		HEART	RESP.	
Injection Drugs on Hand	0007			
Prisoner Entered Chamber	0004			Calm No Problems
Saline Solution IV Set and Running	0009	22		
Chamber Door Locked	0010	96	22	locked & EKG
Drug - Sodium Pentothal Started	0014	96	20	RR 96 RR 18
Drug - Pancuronium Bromide Started	0027	52	0	42
Drug - Potassium Chloride Started	0031			0038 - flat line
Special Comments				PRB - ectopy - flat line
Respirations Ceased	0027			
Cardiac Monitor - Flatline	0038			
Prisoner Pronounced Dead	0038			

Disposition of Remains: